Gamma irradiation as a physical process to pasteurize poultry feed and feed ingredients (feed) by killing Salmonella and other bacterial pathogens.

Nordion International Inc.

FAP 2216

Section H. Environmental Assessment

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Environmental Assessment

Introduction

1. Date:

2. Name of applicant: Nordion International Inc

3. Address: 447 March Road
P.O. Box 13500
Kanata, Ontario K2K 1X8
Canada

Name of Additive and Use: Gamma irradiation as a physical process to pasteurize poultry feed and feed ingredients (feed) by killing Salmonella and other bacterial pathogens.

Submitted to: Food and Drug Administration
Centre for Veterinary Medicine
Director, Division of Animal Feeds (HFV-220)
7500 Standish Place
Rockville, MD
20857

4.0 Description of the proposed action

4.1 The need for action

The undersigned, Nordion International Inc. submits this petition pursuant to section 409 (b) (1) of the Federal Food, Drug and Cosmetic Act with respect to the use of irradiation as a physical process to pasteurize poultry feed and feed ingredients or components (feed) by killing Salmonella, other bacterial pathogens and spoilage organisms. Salmonella and other microorganisms infect poultry causing human and poultry illness and reducing the performance of poultry. Feed is an important vector of poultry contamination. The Food And Drug Administration Center for Veterinary Medicine (FDA-CVM) has stated a goal of zero Salmonella in feed (1). Irradiating pasteurized feed will allow the feed industry to meet that goal. Irradiating pasteurized feed could, therefore, along with other good flock control measures and proper processing methods, reduce Salmonella in poultry and egg products. Salmonella in eggs, and Salmonella, Campylobacter and other bacterial pathogens found in poultry meat commonly cause human illness. We believe, that the irradiation of feed will be a contributing factor to reducing poultry meat contamination levels. To obtain the cleanest, most microbiologically safe poultry meat, irradiation of the poultry meat following the best flock rearing and processing methods is needed. To this end USFDA has approved the irradiation pasteurization of poultry (21 CFR part 179, May 2, 1990 Part VI).

The FDA has determined that for food additives used as components of (1) food contact surfaces of permanent or semipermanent equipment or (2) other food contact articles intended for repeated use, certain parts of the standard Environmental Assessment format paragraph 25.31 a(a) may be abbreviated.

For such food additives, the format of item 6 of the standard format (paragraph 25.31a(a)) is abbreviated by providing the information specified in subparagraph (i) of paragraph 25.31a(b)2, and documentation for items 7 through 11 and 15 has been omitted.(2)

4.2 Locations of production

4.2.1 Geography

Nordion International's Kanata Operation Building is located in the city of Kanata's Industrial Park (Kanata, Ontario, Canada). Nordion has a large parcel of land located at the intersection of Hwy 17B and March Road (old Hwy 17). It is located at the eastern end of March Township, Carleton County, 7 miles west of the Ottawa city

limits and 2 1/4 miles south of the Ottawa River. The site contains three buildings and abuts the property of Theratronics, a company that produces cancer treatment equipment and other equipment on contract, including for Nordion.

Much of the surrounding countryside is still a rural area used for mixed farming and cattle grazing. However, the Kanata subdivision has grown very rapidly over the last several years. The Kanata boundary is 0.5 miles SSE of the site and the hamlet of South March, 1.5 miles NW.

A large number of industrial concerns (e.g. Mitel, Betz, etc.) have also located in the area. Other nearby installations are the Connaught Rifle Range and Shirley's Bay Armed Forces establishment (1.5 miles N) and the Defence Research Board (1.8 Miles E.).

Large sections of the townships in the area are marginal farming land, scrub and bush, with surface outcroppings. To the west and north there are extensive marshy areas.

The Kanata Operation Building houses facilities for the handling, storage, encapsulation, mounting, measurement, and shipping of high-level Cobalt-60 sources. It is located at the northern end of the property, some 400' from NW boundary and 650' from the NE of the Roy Errington Building and 500' NE of the Heating Plant.

4.2.2 Geology

The plant site is on the so-called Ottawa - St. Lawrence lowland, 275' above mean sea level and 75' above Ottawa River at Shirley's Bay. The overmantel consists of glacial till, marine clays and sands, and recent alluvial deposits.

Multiple borings have been made on the site by Selby Subsurface Investigations Company. The water-table varies from 7 to 15' below the surface. In the area where the Cobalt Building is located, there is a layer of moist marine clay to a depth exceeding 50'. The typical stratigraphy of the site is as follows:

0' - 2'	sandy topsoil
2' - 8'	crust or stiff brown clay - damp or dry
8' - 50'	grey clay - both firm and soft - damp
50' to between	

53' and 76' mixed sand, silt, gravel, moist clay, loose to dense.

below 53' granite rock, badly weathered in upper parts.

The findings of some intruded dyke material during boring operation indicates that abrupt surface variations may occur through faulting. The Canada Earthquake Probability map shows the area to be in zone 4.(3)

The Kanata Operation building and its equipment conforms with pertinent requirements of the National Building Code, the Ontario Labour Code, the Dominion Fire Commissioner's Office,the Dominion Board of Insurance Underwriters, the National Board of Fire Underwriters, the National Fire Protection Association, Underwriters Labs of Canada, Underwriters Labs Inc., CSA Approvals Labs, CSA Specifications, CSA-Canadian Electrical Code, Ontario Hydro Electric Commission, the National Capital Commission, the City of Kanata, and other bodies having jurisdiction.

4.3 Location of use

It is not expected that the petitioner, Nordion International Inc. will irradiate feed. Nordion is a leader in developing, producing and marketing radioisotopes and related equipment. Most of our customers are in the health care sector who have medical diagnostic and radiation processing requirements. Other customers are in the food processing industry, broadly defined. Our customers operate contract and dedicated irradiators in the United States and in 45 other countries. We submit this petition to enable us to market industrial irradiation equipment to the feed processing and poultry feed sectors and to assist our customers who want to irradiate poultry feed in existing irradiators. Nordion is not currently and is not expected to be a manufacturer or processor of feed. This function will be carried out by the feed industry or by contract irradiation companies.

We envisage several possible proposed uses for the irradiation of feed:
* The pasteurization of fish meal
* The pasteurization of rendered meal from animal sources used as a feed ingredient
* The pasteurization of meal from plant sources used as a feed ingredient
* The pasteurization of ready-to-eat poultry feed

Given, this assessment then, the locations of use for irradiation equipment could range from off-shore fish meal plants, domestic renderers, or renderer-blender operations, feed ingredient or feed processors, or poultry farm

operations.

The licensing for these irradiation operations will be handled just as they are now. So, just as off-shore medical disposable irradiators and food irradiators are licensed by that country's regulatory authorities, registered by the International Atomic Energy Agency, and subject to inspection by those regulatory authorities plus the regulatory authorities in the United States (or other importing countries), then off-shore fish meal plants would be licensed, registered and subject to inspection in the same way.

Feed ingredient or whole feed irradiation facilities in the United States will first require licensing by the Nuclear Regulatory Commission or by Agreement State regulatory authorities, depending on location. Further information on this is included in Section 6.2.3 of this Environmental Assessment and Appendix C. In addition to these requirements, feed irradiation processing operations would also be subject to all the regulations and inspection pertinent to any feed processing facility.

4.4 Location of long term storage (disposal)

Cobalt-60 sold by Nordion, the leading manufacturer of Cobalt-60 in the world, is returned to Canada when the sources are no longer useful. Nordion guarantees the C-188 (see section 5.2) Cobalt-60 sources for 15 years after which time Nordion agrees to take them back. At the Kanata site Nordion can reprocess the sources for further use or can direct them for long term storage (disposal). By the time spent cobalt is available for disposal by Nordion it typically has 14% of its original activity remaining. At the Cobalt-60 rate of radioactive decay, spent Cobalt-60 will have no more radioactivity than normal background radiation within 250 years. Normal background radiation is the amount of radiation present from natural sources such as soil.

Disposal of spent Cobalt-60, which is considered by AECL to be low-level nuclear waste, takes place at the licensed facility of Atomic Energy of Canada Ltd., Chalk River Nuclear Laboratories in Northern Ontario. The site is regulated, licensed and inspected by the Canada's Atomic Energy Control Board (4, 5).

4.5 List of references and figures

1. Remarks on FDA's program for salmonella negative feeds in Proceedings ad hoc committee on Feed Safety of the United States Animal Health Association San Diego California October 31 1991.

2. ABBREVIATED ENVIRONMENTAL ASSESSMENT
Radiation Sources as Components of Food Surfaces of Permanent or Semipermanent Equipment. FDA Center for Food Safety and Nutrition.

3. Seismic Hazard Calculation, Geofacts, Geological Survey of Canada, Geophysics Division, Ottawa Ontario Canada.

4. Regulatory Objectives, Requirements and Guidelines For The Disposal of Radioactive Wastes - Long-Term Aspect Regulatory Document R-104 Atomic Energy Control Board Ottawa Ontario Canada, June 5 1987.

5. Chalk River Laboratories Amendment No.6 to Licence No. OSL 1/90 Memo Atomic Energy Control Board to Atomic Energy of Canada Ltd

ABBREVIATED ENVIRONMENTAL ASSESSMENT

Radiation Sources as Components of Food-Contact Surfaces of Permanent or Semipermanent Equipment

The FDA has determined that for food additives used as components of (1) food-contact surfaces of permanent or semipermanent equipment or (2) other food contact articles intended for repeated use, certain parts of the standard Environmental Assessment (EA) format (§25.31a(a)) may be abbreviated. For such food additives, abbreviate format item 6 of the standard EA format (§25.31a(a)) by providing only the information specified in subparagraph (i) of §25.31a(b)(2). As provided in subparagraph (ii) of §25.31a(b)(2), documentation is not normally required for standard format items 7 through 11 and 15. Standard format items 1 through 5, 12, 13, and 14 of §25.31a(a) must be addressed in full.

The outline below integrates the standard EA format described in §25.31a(a) with the information required for food additives used as components of (1) food-contact surfaces of permanent or semipermanent equipment or (2) other food contact articles intended for repeated use, under §25.31a(b)(2). The abbreviated format item (6) and the format items for which documentation is not normally required (7 through 11, and 15) are indented.

(2) For approval of food additives to be used as components of food-contact surfaces of permanent or semi-permanent equipment or of other food-contact articles intended for repeated use, the following information is required

§ 25.31a Environmental assessment for proposed approvals of FDA-regulated products—Format 1.

(a) For proposed actions to approve food or color additives, drugs, biological products, animal drugs, and class III medical devices, and to affirm food substances as generally recognized as safe (GRAS), the applicant or petitioner shall prepare an environmental assessment in the following format:

ENVIRONMENTAL ASSESSMENT

1. *Date:*
2. *Name of applicant/petitioner:*
3. *Address:*
4. *Description of the proposed action:* Briefly describe the requested approval; need for the action; the locations where the products will be produced; to the extent possible, the locations where the products will be used and disposed of; and the types of environments present at and adjacent to those locations.
5. *Identification of chemical substances that are the subject of the proposed action:* Provide complete nomenclature, CAS Reg. No. (if available), molecular weight, structural formulas, physical description, additives, and impurities. This information is required to be adequate to allow accurate location of data about chemicals in the scientific literature and to allow identification of closely related chemicals.

6. *Introduction of substances into the environment:*

For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval of the proposed food additive will have upon compliance with current emissions requirements at the production site(s). To determine whether approval of the proposed food additive will result in potentially significant introductions of substances into the environment due to the disposal of food-contact articles containing the proposed food additives, estimate the maximum yearly market volume of the proposed food additive.

See attached additional guidance for format item 6.

7. *Fate of emitted substances in the environment*

8. *Environmental effects of released substances*

9. *Use of resources and energy*

10. *Mitigation measures*

11. *Alternatives to the proposed action*

Documentation for items 7 through 11 is ordinarily not required.

12. *List of preparers:* These persons preparing the assessment together with their qualifications (expertise, experience, professional disciplines) shall be listed. Persons and agencies consulted shall also be listed.

13. *Certification:* The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

(Date) _____

_____

(Signature of responsible official)

(Title) _____

14. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

15. *Appendices:*

Documentation for this item is ordinarily not required.

Because of the unique nature of food irradiation actions, the information requirements for item 6 of the abbreviated EA may be satisfied by providing the following:

1. An identification of the substances expected to be emitted during use of the radiation sources or use of other products involved in the irradiation of foods (e.g., dosimeter materials such as ferrous sulfate and cupric sulfate).

2. A description of any controls exercised to minimize or eliminate occupational and environmental introductions of the substances identified in item 1.

3. A citation of, and a statement of compliance with, specific Federal, State, and local emission requirements, including occupational exposure requirements, applicable to the emissions identified for item 1 (e.g., Nuclear Regulatory Commission (NRC) license numbers for the irradiation facilities, and NRC or State license or permit numbers for the radioactive waste disposal facilities).

4. A discussion of the effect that approval of the proposed action will have upon compliance with current emission requirements.

   If the irradiation facilities have not been determined, tell how you will ensure that selected facilities are licensed and in compliance with all applicable emissions (including occupational exposure) requirements.

Market volume information is not required in item 6 for EAs involving radiation sources.

Geofacts

SEISMIC HAZARD CALCULATION

The damage potential of an earthquake is determined by how the ground moves and how the buildings within the affected region are constructed. Ground motion can be predicted on the basis of probability, which is referred to as seismic hazard.

In Canada, the evaluation of regional seismic hazard for the purposes of the National Building Code is the responsibility of the Geological Survey of Canada. The seismic zoning maps prepared by the Geological Survey are derived from statistical analysis of past earthquakes and from advancing knowledge of Canada's tectonic and geological structure. On the maps, seismic hazard is expressed as the most powerful ground motion that is expected to occur in an area with a given probability. Contours delineate zones likely to experience similar intensities of ground motion.

The seismic zoning maps and earthquake load guidelines included in the National Building Code are used to design and construct buildings as earthquake proof as possible. The provisions of the building code are intended as a minimum standard. They are meant to prevent structural collapse during major earthquakes and thereby to protect human life. The provisions may not, however, prevent serious damage to individual structures.

Seismic Hazard Information in the National Building Code

Building design for various earthquake loads is addressed in sections 4.1.9, 9.20.17 and 9.24.1.5 of the National Building Code of Canada. The seismic zoning maps are found in Chapter 4, Commentary J, Figures J-1 and J-2 of the Supplement to the 1985 edition. In addition, a table in Chapter 1 starting on page 11 of the Supplement provides ground motion design values for some communities across Canada. The National Building Code applies also to existing buildings (Subsection 1.2.1). Annex A (Section A-1.2.1) outlines the principles by which the code should be applied to the use and modification of existing buildings.

The two seismic zoning maps each divide Canada into seven zones of ground motion, one map on the basis of probable ground velocity and the other according to acceleration. Velocity is given in metres per second; acceleration is expressed as a fraction of gravity.

Ground motion probability values are given in terms of probable exceedence, that is the likelihood of a given horizontal acceleration or velocity being exceeded during a particular period. The probability used in the National Building Code is 0.0021 per annum, equivalent to a 10-per-cent probability of exceedence over 50 years. This means that over a 50-year period there is a 10-per-cent chance of an earthquake causing ground motion greater than the given expected value.

Most buildings are well designed for withstanding vertical forces, but the horizontal component of ground motion is critical to earthquake-resistant building design. In the urban areas of coastal British Columbia, for example, 20-per-cent gravity is a typical seismic load at an acceptable probability. A building should be designed to tolerate a sideward pushing force equal to 20 per cent of its own weight.

Calculation of Seismic Hazard

The seismic hazard at a given site is determined from numerous factors.

Canada has been divided into earthquake source regions based on past earthquake activity and tectonic structure. The relation between earthquake magnitude and the

Energy, Mines and Resources Canada
Énergie, Mines et Ressources Canada
Canada

SEISMIC HAZARD CALCULATION

REQUESTED BY: John Doe
ABC Engineering Ltd.

SITE: XYZ Building,
Masset, B.C.

LOCATED AT: 54.00 north, 132.15 west

Probability of exceedence per annum	0.010	0.005	0.0021	0.001
Probability of exceedence in 50 years	40%	22%	10%	5%
Peak horizontal ground acceleration (g)	0.170	0.240	0.344	0.471
Peak horizontal ground velocity (m/sec)	0.245	0.361	0.570	0.733

average rate of occurrence for each region is weighed, along with variations in the attenuation of ground motion with distance. In calculating seismic hazard, scientists consider all earthquake source regions within a relevant distance of the proposed site.

The acceleration and velocity seismic zoning maps show levels of ground shaking over different frequency ranges: centred near 5 hertz (oscillations per second) for the acceleration map and near 1 hertz for the velocity map. This is important because different buildings are susceptible to different frequencies of earth motion, and damage is frequently associated with a resonance between earthquake ground motion and the building's own natural frequency. A high-rise of ten stories or more may sway with a natural period of 1 or 2 seconds, whereas in response to the same ground motion a brick bungalow across the street may vibrate at nearly 10 hertz.

Consequently, low brick buildings can be severely damaged by a moderate (magnitude 5.5) local earthquake that has most of its energy in the high-frequency range. High-rises may be affected more acutely by larger, more distant events. In the Mexican earthquake of 1985, most of the severe damage in Mexico City, 400 kilometres from the earthquake's epicentre, occurred in high-rise buildings with natural peripds near 2 seconds.

In building construction and design, not only the size of a probable earthquake should be considered, but also the nature of the ground motion most likely to occur at the site. Seismic hazard calculations provide part of this information. As our understanding of earthquakes and of their effects on engineered structures continues to develop, the seismic provisions of the National Building Code will be revised to enhance public safety and minimize earthquake losses.

Availability of Seismic Hazard Information

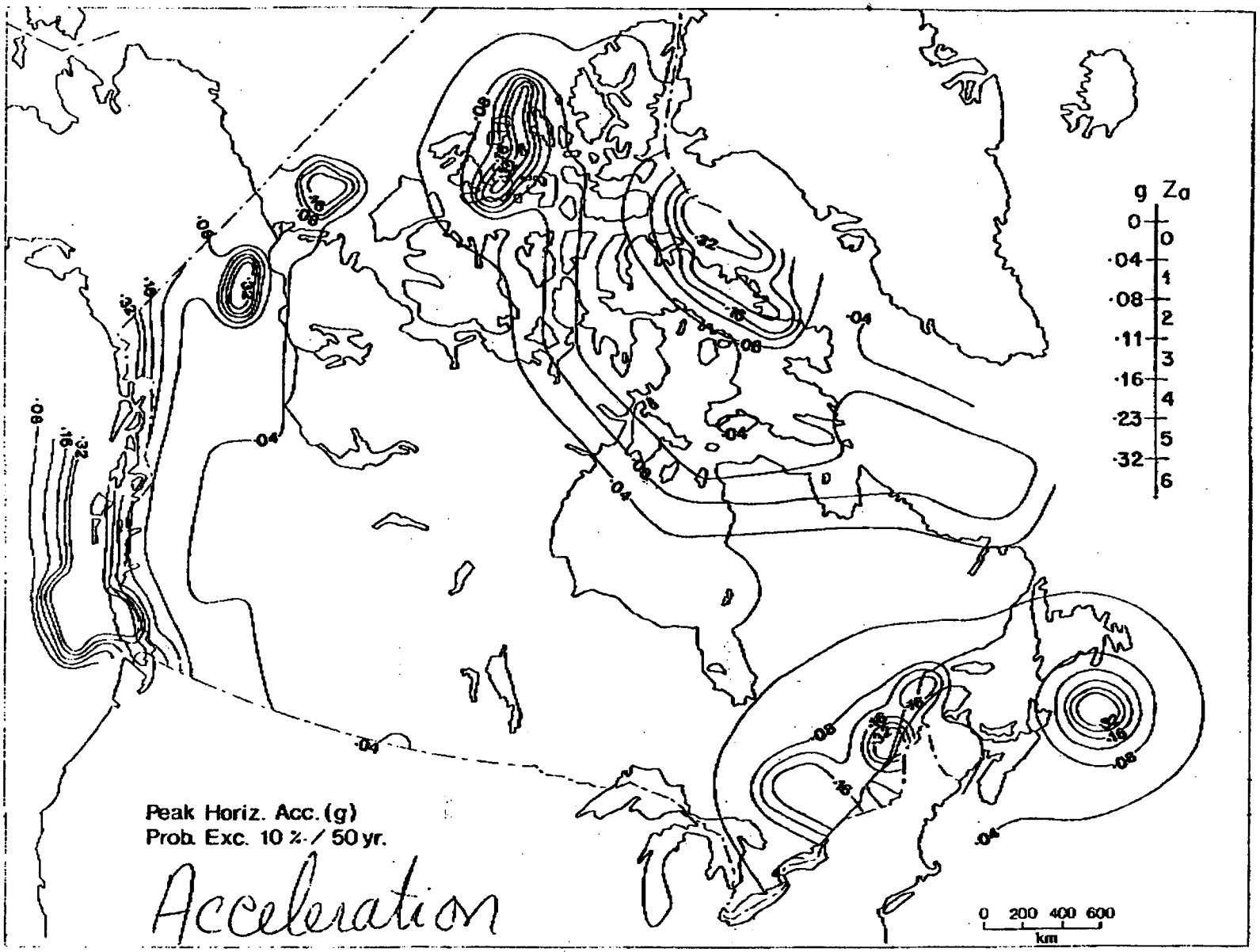
Seismic hazard calculations for sites in Canada are available for $50 per site from the Geological Survey. The peak horizontal ground acceleration and velocity are given for exceedence probabilities of 5, 10, 22 and 40 per cent over 50 years (see example). Requests should provide the latitude and longitude of the site and, if applicable, the name of the construction project.

A detailed discussion of the application of the seismic zoning maps may be found in the article "Engineering Applications of New Probabilistic Seismic Ground-Motion Maps of Canada", by A.C. Heidebrecht, P.W. Basham, J.H. Rainer and M.J. Berry, published in 1983 in the *Canadian Journal of Civil Engineering*, Vol. 10, pages 670 - 680.

For further information, or to request a seismic hazard calculation, please contact:

Geological Survey of Canada
Pacific Geoscience Centre
P.O. Box 6000
Sidney, B.C. V8L 4B2
(604) 356-6500

Geological Survey of Canada
Geophysics Division
1 Observatory Crescent
Ottawa, Ontario K1A 0Y3
(613) 995-5548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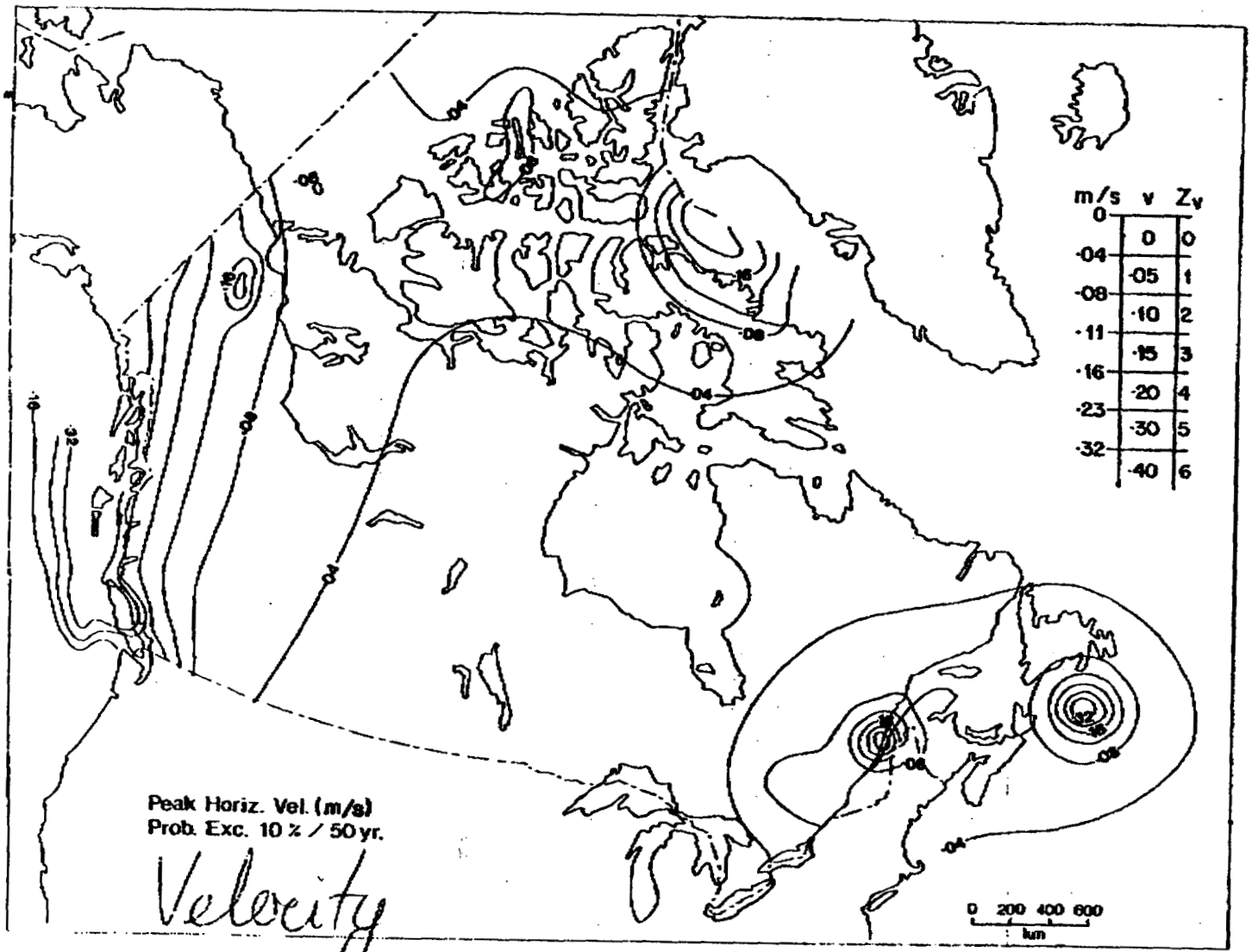

Velocity

Regulatory Document / Texte de réglementation

Atomic Energy Control Board / Commission de contrôle de l'énergie atomique

REGULATORY DOCUMENT R-104

Regulatory Policy Statement

REGULATORY OBJECTIVES, REQUIREMENTS AND GUIDELINES FOR THE DISPOSAL OF RADIOACTIVE WASTES - LONG-TERM ASPECTS

Effective date:

June 5, 1987

Canada

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REGULATORY OBJECTIVES, REQUIREMENTS AND GUIDELINES FOR THE DISPOSAL OF RADIOACTIVE WASTES - LONG-TERM ASPECTS

1. PURPOSE AND SCOPE

It is the purpose of this document to present the regulatory basis for judging the long-term acceptability of radioactive waste disposal options, assuming that the operational aspects of waste emplacement and facility closure satisfy the existing regulatory framework of requirements. Basic objectives of radioactive waste disposal are given, as are the regulatory requirements which must be satisfied in order to achieve these objectives. In addition, guidelines are given on the application of the radiological requirements to assist proponents in the preparation of submissions to the Atomic Energy Control Board (AECB).

The primary focus of the requirements is on radiation protection, although environmental protection and institutional controls are also addressed in a more general way since these factors stem directly from the overall objectives for radioactive waste disposal. Other types of regulatory requirements such as might concern other aspects of conceptual assessments, siting, design, construction, operation and decommissioning of facilities for the management of particular waste types are, or will be, addressed in separate regulatory documents. Examples of these documents are Regulatory Document R-71 on the concept for deep geological disposal of nuclear fuel waste and Consultative Document C-36 on the management of uranium and thorium mine and mill tailings.

2. INTRODUCTION

In Canada, a wide variety of radioactive wastes are generated at all steps in the nuclear fuel cycle from uranium mining and milling to reactor operations for electricity production, and from the use of radioisotopes in industry, research and hospitals. The bulk of these wastes are managed in a manner based on the principles of containment and isolation from people and the environment. However, the techniques employed rely on the continued need for human intervention and surveillance whether this be for monitoring, maintenance, treatment or restriction of public access to assure an acceptable level of radiological safety. The remaining wastes are disposed of either by controlled discharge to the environment as gaseous and liquid effluents, or in the case of small quantities of lightly contaminated material, by treatment as conventional wastes with no requirement for special radiological precautions.

The current operation of radioactive waste management facilities and the routine discharge of radioactive effluents from other nuclear facilities are strictly regulated by the AECB using a comprehensive system of licensing, compliance and enforcement activities. The specific radiological requirements applied by the AECB are derived from the system of dose limitation recommended by the International Commission on Radiological Protection (ICRP). The dose limits recommended by the ICRP are intended to apply to all practices in which radiation exposure of workers and the public can be influenced by active controls but do not apply to exposures from unusual events, medical irradiations and natural background radiation. For exposures from situations such as accidents and other unusual events during nuclear facility operations, the radiological requirements that are applied by the AECB acknowledge the expected frequency of occurrence of the unusual event or process causing the

exposure. In summary, for current operations a regulatory framework of radiological requirements is actively applied, such that procedures of various types are reliably maintained for monitoring environmental discharges, conducting remedial actions as necessary, and controlling exposure pathways.

For the long-term management of radioactive wastes, the preferred approach is disposal, a permanent method of management in which there is no intention of retrieval and which, ideally, uses techniques and designs that do not rely for their success on long-term institutional control beyond a reasonable period of time. The practical disposal options presently being studied usually involve containment of the wastes and their isolation from the biosphere for extended time periods. For some waste types, though, such as the large-volume wastes from uranium mining and milling, the ideal type of disposal may sometimes not be practicable. In such instances where there are no practical disposal options for achieving the ideal goal, there may be a long-term need for continued institutional controls to guard against particular exposure scenarios after the facility has ceased receiving waste and has been closed down.

Whichever option is implemented for the long-term containment and isolation of radioactive wastes, exposures after the closure of a disposal facility will be dependent on a range of events and processes with varying probabilities of occurrence and, in some cases, they will be delayed for considerable periods of time. Forecasts of the possible doses to humans are subject to additional uncertainties owing to the range of factors affecting the environmental transport of radionuclides and to changes which might occur in future living habits, lifestyles and population distributions. Also, in the case of disposal with no ongoing requirement for institutional controls, it is not possible to enforce compliance with present-day forecasts since there would be no operator for the facility in the future. There is consequently a need to establish alternative regulatory requirements to ensure the acceptability of waste disposal options for which there are potential long-term radiological impacts in the post-operational period. The basic purpose of this document is to establish these waste management requirements. For reasons of consistency, equity and fairness, the requirements are based upon an extension of the existing regulatory framework and should be broadly applicable to all waste types and disposal options in which long-term containment and isolation are employed.

It is intended that the requirements and guidelines presented here will come into effect immediately for those facilities designed specifically for the disposal of radioactive wastes. Where a facility may change from an operational storage facility to a disposal facility at some time in the future, the requirements and guidelines are intended to apply at the time disposal is considered to begin. This would normally occur as soon as practical after operations at the facility cease and would likely include a period of institutional control determined by waste and site-specific issues.

3. OBJECTIVES OF RADIOACTIVE WASTE DISPOSAL

The objectives of radioactive waste disposal are to:

- *minimize any burden placed on future generations,*
- *protect the environment,*
- *protect human health,*

taking into account social and economic factors.

Many factors must be considered in meeting these objectives in an effective and reliable way over the long term. The disposal of radioactive wastes on the basis of containment and isolation requires safety features to restrict the release of radionuclides into the environment and to reduce the likelihood of inadvertent public access to the waste. These safety features may incorporate a suitable combination of processes, barriers and institutional controls. The processes include radioactive decay, adsorption, chemical precipitation, dilution, dispersion and other phenomena which influence the transport of radionuclides. The barriers may be provided by engineered design or by the natural geological setting of the site. Such a system of passive multiple barriers gives an increased degree of assurance of containment and isolation and of assurance that any release of radioactive material to the environment will occur at an acceptably low rate. Institutional controls on the other hand are active mechanisms established by society to ensure the continued implementation and achievement of a desired course of action. These controls could include the monitoring and treatment of contaminated releases, the keeping of records, and the imposition of land-use restrictions registered in property deeds and by-laws.

4. BASIC REGULATORY REQUIREMENTS

4.1 Burden on Future Generations

The burden on future generations shall be minimized by:

(a) selecting disposal options for radioactive wastes which to the extent reasonably achievable do not rely on long-term institutional controls as a necessary safety feature;

(b) implementing these disposal options at an appropriate time, technical, social and economic factors being taken into account; and

(c) ensuring that there are no predicted future risks to human health and the environment that would not be currently accepted.

The requirement to minimize the burdens on future generations is based on three matters of principle. The first reflects a pessimistic view of the longevity of institutional controls and concern for the possible consequences should they lapse. Where reasonable disposal alternatives clearly exist, those options which rely on monitoring, surveillance or other institutional controls as a primary safety feature for very long periods are not recommended. This is not because of concern that future generations will be technologically incompetent, but rather because methods of ensuring the continuity of controls are not considered very reliable beyond a few hundred years. Similarly, it is not meant to imply that means to preserve the identity and location of waste disposal facilities or to monitor their performance should not be attempted. It is expected that records will be kept and that in some cases monitoring will be carried out, but, where reasonably possible, safety should not rely on these measures.

The second principle concerns the responsibility of the present generation, as the primary beneficiary of the current exploitation of nuclear energy, to bear

the financial burden associated with the implementation of waste disposal options. It has also been argued, however, that it should be recognized that the current use of nuclear energy contributes to an improved standard of living that will benefit future generations. In any case, the timing of the implementation of waste disposal options will depend on a number of technical, social and economic factors. These include the availability and development of suitable sites and technology, the technical advantages to be gained from interim storage of short-lived wastes and, in the case of used nuclear fuel, the desire not to discard prematurely various constituents that are of potential value to future generations.

The third principle concerns the level of risk that may be imposed on future generations since it is not possible to ensure total containment and isolation and absolute safety. On ethical grounds, and in keeping with the recommendations of the ICRP, the radiological risks to future individuals should be limited on the same basis as are the risks to individuals living now. Moreover, the judgement is made that the level of protection to be afforded to future individuals shall not be less than that which is currently provided.

4.2 Protection of the Environment

> *Radioactive waste disposal options shall be implemented in a manner such that there are no predicted future impacts on the environment that would not be currently accepted and such that the future use of natural resources is not prevented by either radioactive or non-radioactive contaminants.*

One of the primary goals of environmental protection is to ensure appropriately safe conditions for human activities. This includes the impacts on human health arising from non-radioactive substances which may also be released from waste disposal facilities. It is thought likely that the level of radiation protection afforded all human individuals ensures adequate protection of other living species in the environment, although not necessarily individual members of those species. It follows then that by establishing the requirements found in this document concerning the radiation health burden on future generations, an appropriate requirement for environmental radiation protection is also formulated.

However, there is also a need to provide adequate protection for the general environment from the impacts that might arise from either radioactive or non-radioactive contaminants. The disposal of radioactive wastes must therefore comply with the appropriate requirements governing land-use and the protection of natural resources, such as water, wildlife, fish, soil, forests, minerals and other economically viable commodities. This basic requirement applies both to the environment surrounding a waste disposal facility and to the materials consumed in its construction and operation.

4.3 Protection of Human Health

The primary focus in this section is on radiological aspects of human health. It must however be recognized that some non-radioactive substances also may have detrimental effects on health. These effects have already been addressed in Section 4.2.

4.3.1 General Requirement

The predicted radiological risk to individuals from a waste disposal facility shall not exceed 10^{-6} fatal cancers and serious genetic effects in a year, calculated without taking advantage of long-term institutional controls as a safety feature.

In judging the acceptability of a disposal facility for which forecasts of hypothetical exposures of individuals in the future are made, it is not appropriate to apply dose limits in the manner practised today for the current operation of nuclear facilities. This is because it will not generally be possible in the long term to enforce compliance with any preselected dose limits. There is also considerable uncertainty as to whether the doses forecast will actually be received. This is due to the assumptions and uncertainties in predictive assessments concerning, for example, the location of the exposed individuals. It is also clear that waste disposal facilities may be subject to unlikely events and processes which could cause doses in excess of an individual dose limit. For example, seismic or tectonic phenomena can modify groundwater flow characteristics, and flooding and erosion may have a disruptive effect on near-surface facilities. Similarly, future human activities such as well-drilling, mineral exploitation, building and farming could give rise to immediate radiation impacts and could modify the characteristics of existing environmental pathways as well as introduce new pathways.

In order to take into account the hypothetical exposures committed in a year from both highly probable and less probable events and processes, the appropriate expression of the requirement is in terms of risk, where risk is defined as the probability that a fatal cancer or serious genetic effect will occur to an individual or his or her descendants. Risk, when defined in this way, is the sum over all significant scenarios of the products of the probability of the scenario, the magnitude of the resultant dose and the probability of the health effect per unit dose. Where it is reasonable to assume that the probability of the scenario approximates unity, the risk is simply the product of the dose and the probability of the health effect per unit dose. This is often assumed to be the case for groundwater transport of radionuclides to the human environment in the long term from a waste disposal facility.

For lifelong continuous exposures, the present view of the ICRP is that the principal limit on effective dose equivalent to members of the public should be 1 millisievert (1 mSv) in a year, taking into account exposures from all sources and facilities excluding medical irradiations and natural background radiation. Since the probability of fatal cancers and serious genetic effects is approximately 2×10^{-2} per sievert, the probability of these health effects associated with a dose of 1 mSv is 2×10^{-5}.

In the case of a single waste disposal facility, there is a need to ensure that the predicted radiological risks associated with it are sufficiently low so as to allow for uncertainties in exposure scenarios and their consequences, and also to allow for future nuclear activities which might impact on the same individuals. An appropriate and prudent risk level for individuals must therefore be chosen in keeping with the objective concerning the radiological

health burden on future generations. The level of risk selected, 1×10^{-6}, or 1 in a million, in a year, is a level of risk from other activities that is considered to be insignificant by individuals in their daily lives.

To put the foregoing into perspective, a risk of 10^{-6} in a year is the risk associated with a dose of 0.05 mSv in a year. Individual doses of 0.05 mSv in a year are a small fraction (approximately 2.5%) of the annual dose received by the general population in Canada from natural background radiation and are also of the same order of magnitude as the doses to critical groups predicted from the routine release of radioactive effluents from nuclear power reactors in Canada.

4.3.2 Variance From the General Requirement

> *If there is no practicable method of fully meeting the requirements of Section 4.3.1, an optimization study shall be performed in order to determine the preferred option. A disposal facility, under these circumstances, shall be:*
>
> *(a) compatible with the results of such a study, and*
>
> *(b) such that the predicted risk to individuals does not exceed that which is presently accepted from current operations involving the same wastes.*

It is clearly the intent of this document to have the general requirement used as the basis for judging the acceptability of human health protection to the greatest extent practicable. However, for some waste types in a site-specific situation, there may be no realistic alternative to their disposal in a manner which requires long-term institutional controls as a safety feature. Uranium mill tailings are a general class of wastes which are generated in large volumes and which, in most practicable disposal options, require some form of long-term institutional control to guard against the occurrence of particular exposure scenarios. This need arises since the tailings disposal options usually involve some variation of surface or near-surface containment. In this case, measures must be implemented to deter inadvertent public access to or misuse of the waste material. Moreover, monitoring, surveillance and maintenance may be needed to ensure satisfactory long-term performance. The existence of institutional controls may also permit future societies to take remedial action if that is considered desirable. However, in keeping with the requirement concerning the burden on future generations, the need for such controls must be minimized to the extent reasonably achievable. The process of determining what is reasonably achievable is called optimization and is discussed in greater detail in Section 5.5. The stipulation that the predicted risk to individuals not exceed that which is presently accepted from current operations involving the same wastes follows from the requirement concerning the burden on future generations. It should be ensured that when the long-term risk predicted to arise from a waste disposal facility is compared to presently-accepted risks, a similar set of scenarios, critical groups and overall assumptions are used, so that artificial differences between predictions of consequences for today's practices and those in the future are avoided.

5. GUIDELINES FOR APPLICATION OF THE BASIC RADIOLOGICAL REQUIREMENTS

5.1 Identifying the Individual of Concern

The individual risk requirements in the long term should be applied to a group of people that is assumed to be located at a time and place where the risks are likely to be the greatest, irrespective of national boundaries.

The concept of the critical group is commonly employed when applying individual dose limits to members of the public affected by existing nuclear facilities. This concept involves the identification of a relatively homogeneous group of people that is expected to receive the greatest exposure because of its location, age, habits and diet. Owing to the conservative assumptions usually made in selecting critical groups and in defining their lifestyles, the doses actually received by members of the group will in most cases be lower than the estimated mean dose of the critical group. It follows that doses to individuals outside the critical group are even lower.

When considering potential exposures in the future, the precise identification of critical groups and their lifestyles is not possible because of uncertainties about population distributions, living habits, climate and other aspects of the environment. In these circumstances, the individual risk requirements in the long term should be applied to a critical group of people that is assumed to be located at a time and place where the risks are likely to be the greatest regardless of national boundaries. This ensures that individuals beyond the national border are afforded a level of radiation protection at least as stringent as the level afforded residents of Canada.

Definition of the lifestyle of the hypothetical group of people should be based on present human behaviour using conservative, yet reasonable, assumptions. Similarly, the diet and metabolic characteristics of the group should be based on present knowledge, making the assumption that the basic dietary requirements of future individuals will be the same as those of people at present.

5.2 Probabilities of Exposure Scenarios

The probabilities of exposure scenarios should be assigned numerical values either on the basis of relative frequency of occurrence or through best estimates and engineering judgements.

In order to apply the risk requirements it is necessary to express the probabilities of exposure scenarios quantitatively. While the term "probability" is usually defined in terms of relative frequency of occurrence, the conventional system for assigning probabilities breaks down as the frequency of occurrence decreases, since little information exists on which to base predictions. Low probability exposure scenarios should therefore be assigned values through best estimates and engineering judgements. These values can be determined using a subjective probability approach in which a number is assigned to the likelihood of an event occurring in a defined period of time, as a measure of the degree of belief that the event will actually occur during that time. The assignment should be made using quantitative analytical techniques to

assess as broad a base of expert opinion as reasonably possible. The use of subjective probability is appropriate as long as the quantitative values assigned through best estimates and engineering judgements are consistent with the quantitative values of the actual relative frequencies in situations where more information is available. The uncertainty of the probability assigned should also be estimated.

5.3 Timescale of Concern

> *The period for demonstrating compliance with the individual risk requirements using predictive mathematical models need not exceed 10,000 years. Where predicted risks do not peak before 10,000 years, there must be reasoned arguments that beyond 10,000 years the rate of radionuclide release to the environment will not suddenly and dramatically increase, and acute radiological risks will not be encountered by individuals.*

Demonstration that a radioactive waste disposal facility complies with the individual risk requirements can only be done by forecasting future impacts using predictive mathematical modelling techniques. In any assessment of the performance of waste disposal options there are several general sources of uncertainty associated with parameter values, the mathematical models and the specification of environmental pathways and exposure scenarios. In general, these uncertainties will increase as the period of prediction increases. On the other hand, the uncertainties are partially offset in that the potential hazard associated with radioactive wastes usually decreases with time owing to radioactive decay of the source, unlike the potential hazard from many types of toxic chemical wastes which do not decay.

In view of the increasingly speculative and uncertain environmental conditions that might exist in the future, estimates of individual risk in the far future may be subject to considerable error, given that environmental modelling is a key part of risk assessment. For example, if severe changes in global climate were to occur, the human environment would also drastically change from that which exists today. It is therefore considered appropriate for regulatory decision-making purposes to establish an upper bound on the timespan for individual risk calculations.

Selection of an upper bound, however, is a matter of judgement since there does not appear to be any objective way of limiting the assessments in a scientifically satisfying manner. Taking into account the characteristics of radioactive wastes, the options for their disposal, and the uncertainties in long-term predictions, it is considered that 10,000 years after the time of waste emplacement is a reasonable maximum period for assessments of individual risk.

For some waste types and disposal options, shorter time periods than 10,000 years for predictive modelling are all that are necessary. This is particularly true where radioactive decay or radionuclide release and dispersion are predicted to occur to the extent that risks to individuals are clearly on the decline. For other situations, assessments may show that the predicted risks to individuals do not peak before 10,000 years. This might occur where long-lived wastes are contained and isolated in geological formations that are relatively unaffected by natural surface phenomena and that are likely to remain stable

over extended timescales. In these cases, there must be reasoned argument leading to the conclusion that beyond 10,000 years sudden and dramatic increases in the rate of release to the environment will not occur, acute doses will not be encountered by individuals and that major impacts will not be imposed on the biosphere.

To put the maximum period of 10,000 years for assessment into perspective, it should be recognized that a number of experts believe that the next glacial episode will commence as early as several to tens of thousands of years from now. In the event of glaciation, it can be expected that near-surface wastes in Canada will be dispersed and diluted in the environment by the movement of ice sheets. It is also reasonable to assume that humans would avoid a heavily glaciated region during an ice age although they would likely repopulate the region when glaciers recede many thousands of years later. Wastes at greater depth will be less affected by glaciation, depending on their depth below the surface and the nature of the geological host formation. For example, the evidence suggests that a deep geological repository for nuclear fuel wastes in hard crystalline rock would not be breached by the erosional effects of glaciation, although the regional groundwater flow system would likely be modified.

5.4 Output From Predictive Modelling

Calculations of individual risks should be made by using the risk conversion factor of 2 x 10^{-2} per sievert and the probability of the exposure scenario with either:

(a) the annual individual dose calculated as the output from deterministic pathways analysis; or*

(b) the arithmetic mean value of annual individual dose from the distribution of individual doses in a year calculated as the output from probabilistic analysis.

There are two general approaches to mathematically modelling the long-term performance of waste disposal facilities, but it must be recognized that in either the deterministic or the probabilistic approach the results can only represent an approximation of the consequences, were releases of radionuclides to occur. Confidence in the modelling output must then derive from a thorough examination of the assumptions, input data and mathematical models constructed to represent the release and transport of radionuclides and the subsequent exposure of individuals. Such an examination can be accomplished by a combination of several complementary methods. These include:

(a) the use of an appropriate quality assurance program in the development, application and maintenance of computer models and in the gathering, interpretation and incorporation of data;

(b) the use of experimental laboratory and field techniques for the validation of models and parameter values to the extent possible;

*dose means the effective dose equivalent committed per year of exposure

(c) peer review by independent experts; and

(d) intercomparison of various modelling approaches.

In the traditional deterministic approach, a single value for each of the model parameters is selected from a range of input values to produce a single value of model output, usually in terms of annual individual dose which is the consequence of primary interest. When using this technique, conservative assumptions are usually made to compensate for the uncertainty in modelling and to ensure that the calculations overestimate the potential doses from possible releases from a facility. Excessive conservatism however is not to be used and a balanced choice of assumptions is to be made to ensure that the overall assessment describes reasonable situations encompassing the full spectrum of exposure pathways, and assesses their impacts in a rational manner. Where complex systems are being modelled, sensitivity analyses should be conducted to investigate the effect of changes in the values of model parameters on the magnitude of the dose estimate, particularly when the estimated dose is judged to be significant. Comparisons with the risk requirements are then straightforward provided that the probabilities of exposure scenarios have been properly assigned.

Another approach now available involves probabilistic assessment techniques in which each parameter value is randomly selected from its probability distribution for input to the model. By repeating the analysis many times, a distribution of consequences is obtained which represents the spread and variation of outcomes as a result of variability and uncertainty in input parameter values for a particular scenario. This approach has certain advantages over the traditional deterministic approach by providing more information. A frequency distribution of individual dose will usually display a most probable dose value and a maximum dose value in the high-tail extremity of the distribution and thus it is necessary to specify a means of comparing the output to the risk requirement. In this case, the arithmetic mean value of the distribution should be calculated and should be taken as being representative of the consequences predicted for an exposure scenario, such as that involving groundwater transport of radionuclides to the environment. In the same way as for deterministic assessments, sensitivity analyses should also be conducted to investigate the effect of changes in input assumptions and model parameters on the mean value of dose. The latter should then be combined with both the probability of the exposure scenario and the risk conversion factor for comparison with the individual risk requirements.

By calculating the arithmetic mean value of the frequency distribution of dose, the significance of the extreme values may be overlooked. Since some of these could conceivably result from combinations of reasonable parameter values, this would clearly be undesirable even though the fact that such combinations generate consequences in the tail-end of the distribution is indicative that their relative frequency of occurrence is low. Nonetheless, the relative frequencies of occurrence of high consequences may differ significantly between frequency distributions having the same mean value. An additional criterion appears to be needed to help judge the acceptability of an option for which probabilistic environmental pathways analysis calculates high doses, albeit with a low relative frequency. It is judged acceptable to allow 5% of the estimated doses to exceed a dose of 1 mSv per year to take account of normal statistical variations which are inherent in the probabilistic assessment process. However

the choice of the general risk requirement takes account of this since a 5% occurrence of a dose of 1 mSv corresponds to an average dose of 0.05 mSv. If more than a 5% level of occurrence is predicted at 1 mSv or higher doses, then the criterion for the arithmetic average itself cannot be met. Thus for the numbers chosen in this regulatory policy statement a secondary requirement is not specifically needed but is implied and needs to be specifically addressed in proposals.

5.5 Optimization

When an optimization study is required in accordance with Section 4.3.2, it should take account of all relevant radiological and non-radiological factors.

The ICRP principle that all exposures should be as low as reasonably achievable, taking social and economic factors into account, may be regarded as being generally applicable. However, for the purposes of this regulatory document it is to be applied only to the disposal of radioactive wastes where the general risk requirement is not likely to be met and thus where continuing long-term institutional controls are necessary. In other cases, the risk limit is sufficiently low to be the primary requirement with optimization playing at most a secondary role to help guide broader choices between options. Application of the optimization principle is intended to ensure that all reasonable or practical opportunities to reduce doses are explored in a broad way. The factors to be considered may include both radiological and non-radiological aspects, human health and environmental protection, as well as a broad range of social and economic issues. For example, it is appropriate to consider both public and worker risks associated with each step of the sequence of activities involved in waste disposal and not simply the risks to individuals in the long term. Also it may be necessary to weight some factors to take account of preferences such as might apply to spatial and temporal distributions of risk and other radiological parameters. Some non-radiological factors include, but are not limited to, conventional safety, environmental impacts, transportation, the nature and length of any institutional controls and the susceptibility of disposal options to naturally occurring disruptive events and to human intrusion. Some of these factors will not be amenable to rigorous quantification and thus a full optimization study will require the use of considered judgement. There are various techniques which can help structure this type of analysis so that the choices which need to be made are clear and the rationale for each choice can be fully documented. Generally, optimization in this broad sense does not result in clear or unambiguous choices between disposal options in the long term. It is for this reason, and the fact that the general risk requirement is so low, that optimzation has not been given a prominent role in this document.

AECL EACL

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1992 March 20

Ms. Michelle Marcotte
Market Development Division
Nordion International Incorporated
447 March Road
KANATA, Ontario
K2K 1X8

Dear Ms. Marcotte:

A copy of the site licence NRTE 1/91 as issued to Chalk River Laboratories by the Atomic Energy Control Board is attached. You will notice that the Waste Management Area is located in the list in Appendix A.

If you have any further questions, please contact me.

Yours truly,

D.A. Barrington
Branch Manager

DAB/jjy
Enc.

Atomic Energy Control Board
Commission de contrôle de l'énergie atomique

Ottawa Canada
K1P 5S9

Your file Votre référence

Our file Notre référence
24-0-0-0
24-1-0-0

ATOMIC ENERGY OF CANADA LIMITED
344 Slater Street
Ottawa, Ontario
K1A 0S4

CHALK RIVER LABORATORIES

NUCLEAR RESEARCH AND TEST ESTABLISHMENT

LICENCE NO. NRTE 1/91

The Atomic Energy Control Board (hereinafter referred to as "the Board") hereby authorizes Atomic Energy of Canada Limited (hereinafter referred to as "AECL") to operate the Chalk River Laboratories (hereinafter referred to as "CRL") located on the site described in the schedule to the Board Order 1/14/74 dated 4 June 1974 published in Part I of the Canada Gazette for June 8, 1974 and comprising the facilities described in:

a) Appendix "A", and

b) the document entitled "Documentation in Support of Site Licence Renewals for the Chalk River and the Whiteshell Laboratories", numbered RC-693, and dated September 1991 (hereinafter referred to as "RC-693").

AECL is further authorized to possess, refine, import or use any prescribed substance and to possess or use any device or equipment containing any prescribed substance within the boundaries of CRL and to sell prescribed substances or any device containing a prescribed substance (all of which are hereinafter collectively referred to as "the licensed activities").

The operation of CRL and the conduct of the licensed activities authorized by this licence are subject to the following conditions with which AECL shall comply.

1. a) The operation of CRL and the conduct of the licensed activities shall be governed by and be in accordance with the documents prepared by AECL and listed in Appendix "B".

b) The documents referred to in Appendix "A" and condition 1(a) shall not be amended except with the written approval of the Board.

Canada

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Envoy: AECBREG

2. Operations, reports, tests, inspections, analyses, modifications, or procedural changes requested by the Board shall be completed or submitted within the time stipulated by the Board.

3. All laws of general application from time to time in force in the Province of Ontario, and pertaining to health, safety, security or protection of the environment, are applicable to and in respect of CRL and shall be complied with by AECL except to the extent that such laws conflict with any condition of this licence or any federal statute or any order, rule or regulation made thereunder.

3.1 Without limiting the generality of condition 3, AECL shall:

a) in accordance with the requirements of the Ontario Boilers and Pressure Vessels Act and the regulations made pursuant to that Act, design, construct, test, inspect, install, and operate boilers, pressure vessels, plant, and any additional part thereof that may be specific by the Board; and

b) provide access at all reasonable times to inspectors from the Ontario Ministry of Consumer and Commercial Relations for the purposes of conducting inspections pursuant to the Ontario Boilers and Pressure Vessels Act and the regulations made pursuant to that Act.

4. a) AECL shall establish and maintain on-site emergency procedures satisfactory to the Board.

b) AECL shall make arrangements with off-site emergency authorities satisfactory to the Board.

c) The procedures and arrangements referred to in conditions 4(a) and 4(b) shall be reviewed at least annually by AECL.

5. a) The rate of release of prescribed substances from CRL shall be monitored and controlled and such releases in any week as airborne effluents and in any month as liquid effluents shall not exceed the weekly and monthly limits respectively identified in the document referenced in paragraph 2 of Appendix "B".

b) The release of prescribed substances from CRL as airborne and liquid effluents shall be monitored by AECL to demonstrate compliance with condition 5(a).

6. Maximum permissible doses of ionizing radiation shall be as set out in Schedule II of the Atomic Energy Control Regulations (hereinafter referred to as "the regulations"), but notwithstanding the permissible doses in the regulations, AECL shall ensure that CRL is operated in such a manner that doses of ionizing radiation will be as low as reasonably achievable, social and economic factors being considered.

7. A copy of this licence shall be available for examination by personnel of CRL and a notice of licensing acceptable to the Board shall be prominently displayed in buildings 401 and 500.

8. Persons appointed under Section 12 of the regulations shall at all reasonable times be provided access to CRL and to all plans, drawings, documents and records pertaining to the design, construction, testing, operation and decommissioning of the facilities described in Appendix "A" to this licence and pertaining to the conduct of the licensed activities.

9. AECL shall maintain security measures acceptable to the Board for protecting the facilities described in Appendix "A" to this licence and for preventing theft, loss or any unauthorized use of prescribed substances associated with the operation of CRL or with the conduct of the licensed activities.

10. Without limiting the applicability of any other condition of this licence to the operation of a facility listed in Appendix "A",

    a) the operation of each facility listed in Column 1 of Part A.1 of Appendix "A" shall be governed by and be in accordance with the section of the document corresponding to that facility specified in Column 2; and

    b) the operation of each facility listed in Part A.2 of Appendix "A" shall be within the limits set out in the document referenced in that Part.

11. a) Except as otherwise directed in writing by the Board, AECL may not construct, install or modify buildings, structures, equipment, or alter procedures at CRL unless such construction, installation, modification or alteration has been

        i) approved in accordance with the documents referred to in Appendix "C"; and

        ii) in the case of a construction, installation, modification or alteration which could result in a hazard different in nature or greater in magnitude or probability than that stated in or inferred from RC-693 or the documents referred to in Appendix "A", approved by the Board in writing.

    b) The documents referred to in condition 11(a)(i) shall not be amended except with the written approval of the Board.

12. AECL shall ensure that there are in attendance at CRL and at the facilities listed in Appendix "A", qualified personnel that are sufficient in the opinion of the Board, to ensure at all times the safe operation of CRL and of those facilities.

13. Except as otherwise directed in writing by the Board, every system associated with a facility referred to in condition 10 shall be tested at a frequency, sufficient in the opinion of the Board, to substantiate the reliability that is claimed or implied in RC-693 or the document respecting that facility referred to in condition 10.

14. Maintenance of every facility, as referred to in condition 10, shall be of such a standard and frequency that the reliability and effectiveness claimed by AECL in respect of all equipment and systems in RC-693, or in the applicable section of the document referred to in condition 10, is assured.

15. AECL shall ensure that its personnel, who are allowed or required to handle prescribed substances, have been trained in the safe handling of such substances.

16. AECL may make shipments of prescribed substances, or devices containing prescribed substances, in Canada only to persons who are authorized by the regulations to possess such substances.

17. AECL shall not ship a prescribed substance, as referred to in Column 1 of Appendix "D" to this licence, outside the boundaries of CRL except in accordance with a transit security plan approved in writing by the Board.

18. AECL shall promptly make reports to the Board of any:

a) failure of equipment or procedures which led to or which, in the absence of safety systems provided, could have led to significant fuel failure in a reactor or any release of radioactive material from any facility described in Appendix "A" to this licence exceeding the derived release limits referred to in condition 5;

b) failure of a protective system which did or could prevent the system from performing in accordance with RC-693 or the document referred to in condition 10;

c) occurrence or series of occurrences which led, might have led, or might lead to any person receiving a dose of ionizing radiation exceeding the limits prescribed in Schedule II of the regulations;

d) degradation, weakening or incipient failure of components or systems whose failure would constitute or significantly increase the risk to the health and safety of any person or to the environment;

e) inaccuracy or incompleteness in the documents referred to in conditions 1, 5 and 10 which could affect the results of the safety assessment in these documents;

f) hazard different in nature or greater in probability or magnitude than that described in the document referred to in condition 10;

g) attempted or actual breaches of security, threats and attempted or actual acts of sabotage;

h) event which constitutes or reveals a violation of any conditions of this licence, the Physical Security Regulations, the Atomic Energy Control Regulations; or the Transport Packaging of Radioactive Materials Regulations; or

i) actual or impending instances of industrial disputes or civil demonstrations which could affect the safety or security of CRL or the facilities listed in Appendix "A".

19. AECL shall prepare and submit to the Board at regular intervals acceptable to the Board, reports that cover:

a) the operation and maintenance of the facilities listed in Part A.1 of Appendix "A" summarizing facility and equipment performance and changes, changes to operating policies, changes in organization, occurrences described in condition 18, personnel radiation exposures and releases of radioactive prescribed substances from the facilities;

b) the review of the procedures and arrangements referred to in condition 4(c);

c) the results of the effluent monitoring referred to in condition 5(b) and personnel radiation exposures for the CRL site;

d) the results of environmental monitoring.

20. Except as otherwise directed or approved by the Board in writing:

a) the reports described in conditions 19(a), 19(b) and 19(c) covering the preceding calendar year shall be submitted to the Board by March 31 of each year, and

b) the reports described in condition 19(d) covering the preceding calendar year shall be submitted to the Board by April 30 of each year.

21. AECL shall establish and maintain an accounting and reporting system for uranium, thorium and plutonium in accordance with Board document AECB-1049/Rev-2(E), "Reporting Requirements for Fissionable and Fertile Substances" attached as Appendix "E" to this licence.

22. For prescribed substances other than those referred to in condition 21, AECL shall keep records that describe fully and accurately:

a) the amount and type of radioactive prescribed substances released from CRL into the environment,

b) the amount, type and location of radioactive prescribed substances placed into or removed from each waste management site, and

c) the production, acquisition and disposition of prescribed substances other than those referred to in (a) and (b).

23. AECL shall submit every three months, a report on the progress of improving and updating the documentation listed in RC-693.

This licence comes into effect 18 December 1991 and unless sooner suspended or revoked expires on the 30th day of June 1994.

DATED at OTTAWA, this 16th day of December 1991.

ATOMIC ENERGY CONTROL BOARD

BY R.J.A. Lévesque
President

CRL LICENCE NO. NRTE 1/91

APPENDIX "A"

LIST OF FACILITIES COMPRISING CHALK RIVER LABORATORIES

PART A.1

Facilities identified below together with the applicable sections of Part I of the document entitled "Principles and General Rules for the Operation of AECL Nuclear Facilities", numbered AECL-MISC-191, prepared by Atomic Energy of Canada Limited.

Column 1 Facility	Column 2 Applicable section and date of issue or revision
NRU Reactor	Section A (1990 May)
NRX Reactor	Section B (1986 August)
Recycle Fuel Fabrication Laboratory	Section C (1988 May)
PTR Reactor	Section D (1988 May)
ZED-2 Reactor	Section E (1988 May)
Building 234 Universal Cells	Section F (1986 August)
Mo-99 Production Facility	Section G (1991 August)
Industrial Materials Processing Electron Accelerator (IMPELA)[a]	Section K (1989 May)
Pulsed High Energy Linear Accelerator Facility (PHELA) [a]	Section L (1989 May)
Tandem Accelerator Superconducting Cyclotron	Section O (1989 May)
Health Physics Neutron Generator	Section P (1986 November)
FINS Neutron Generator	Section Q (1986 November)
Waste Treatment Centre	Section T (1989 August)
Fuels and Materials Hot Cell Facility	Section U (1988 May)
Waste Management Areas	Section V (1989 November)
Nuclear Fuel Fabrication Facility (Bldg 405)	Section X (1990 February)

(a) In addition to IMPELA and PHELA, there are two other accelerators at CRL that are described in Appendix 8 of RC-693.

PART A.2

Facilities listed below and described in the document entitled "Significant Facilities at Chalk River Nuclear Laboratories not covered by Principles and General Rules", numbered AECL-MISC-278, dated August 1986 and prepared by AECL.

1. The fuel fabrication facility located in building 429.

2. The heavy water upgrading facility located in building 210.

CRL LICENCE NO. NRTE 1/90

APPENDIX "B"

DOCUMENTS PERTAINING TO OVERALL OPERATION

1. "Summary of CRNL Operational Radiation Protection Standard Practices" by R.L. Nowell, numbered AECL-MISC-282 and dated 1987 March.

2. "Derived Release Limits (DRL's) for Airborne and Liquid Effluents from the Chalk River Nuclear Laboratories during Normal Operation", numbered AECL-7243, dated 1981 February.

CRL LICENCE NO. NRTE 1/91

APPENDIX "C"

1. "Nuclear Safety Advisory Committee Review and Approval of Nuclear Facilities", Standard Policies and Procedures, Company-Wide Series Number RCW-3.06 dated 1987 April.(a)

2. Subsections A1, A2, A3, A4.1, A4.2, B(a)1, B(a)2, B(a)3, B(a)4.1, B(b)1, B(b)2, B(b)3, B(b)4.1, B(c)1, B(c)2, B(c)3, B(c)4.1 and B(c)4.2 of Annex III of the document entitled "Organization of AECL as Regards the Control of Health, Safety and Environmental Aspects of Nuclear Energy," numbered AECL-MISC-163, dated 1987 November.(a)

(a) The Nuclear Safety Advisory Committee has been replaced by the Safety Review Committee.

CRL LICENCE NO. NRTE 1/91

APPENDIX "D"

Item	Prescribed Substances Column 1	Quantities		
		Column 2	Column 3	Column 4
1.	Unirradiated Plutonium or U-233	2 kg or more	Less than 2 kg but more than 500 g	500 g or less but more than 15 g
2.	Unirradiated U-235, in uranium enriched in U-235			
	(a) 20% or more	5 kg or more	Less than 5 kg but more than 1 kg	1 kg or less but more than 15 g
	(b) 10% or more but less than 20%	not applicable	10 kg or more	Less than 10 kg but more than 1 kg

Note to Appendix "D": For the purposes of this Appendix, an unirradiated substance is a substance that has not been irradiated in a reactor or a substance that has been irradiated in a reactor but which has a radiation level equal to or less than 100 rad (one gray) per hour measured at a distance of 1 m in air from the substance.

5.0 Identification of the chemical substances that are the subject of the proposed action

5.1 Name and identity

Cobalt is a silver-white metal similar to nickel and iron. Its symbol is "Co" and its atomic weight is 59. The number, 59, is the sum total of all the protons (27) and neutrons (32) in naturally occurring cobalt. Cobalt is a stable, non-radioactive element and can be found in rock formations in many countries, including Canada (1). It is magnetic with permeability of about two-thirds that of iron. Its density is 8.9 g/cm^3 , melting point 1495°C, boiling point 2900°C (2).

Cobalt-60 is generated by placing Co-59 in a nuclear reactor. Each atom of cobalt-59 that absorbs one (thermal) neutron is transformed into cobalt-60 (3). The chemical properties of Cobalt-60 are identical to those of cobalt 59.

Canadian Deuterium Uranium (CANDU) reactors, designed and developed in Canada, are used as suppliers on contract to Nordion to produce Cobalt-60. Cobalt-60 is not a radioactive waste or a by-product of CANDU reactors. It is purposely produced (1).

5.2 Composition of Cobalt-60 sources

A typical cobalt capsule is shown on Figure 1. 99.9% pure cobalt 59 slugs are nickel-plated and welded into a Zirconium alloy (zircalloy) "Inner Capsule". Inner capsules are assembled into Reactor Target Bundles and placed into reactors for activation (conversion of Co-59 to Cobalt-60). After activation, target bundles, now containing approximately 90% cobalt 59 and 10% Cobalt-60 are extracted from the reactor into a shielded flask and transferred into a ten-meter deep water-filled storage bay where they are transferred into an approved shipping container. Next, they are transported to Nordion's cobalt processing facility in Kanata Ontario, Canada where the bundles are dismantled in a 20 m deep water filled pool. The zircalloy inner capsules are sealed into stainless steel "Outer Capsules" in shielded cells. This is the C-188 Cobalt-60 source (Figure 1).

To improve corrosion resistance, the outer capsules are made from ASTM 316 L stainless steel which, due to its low carbon content permits welding with minimum carbide precipitation (4).

5.3 Physical and chemical properties

Cobalt-60 has a half-life of 5.26 years, meaning that within this time period, the radioactivity reduces through decay to one-half its original value. When Cobalt-60 decays to nickel 60 energy is released in a step-wise reaction through excited energy states of its nucleus. During this process, beta energy is given off to a maximum energy of 0.313 MeV. This radiation is not very penetrating it is absorbed by the encapsulating material. Most of the energy released in the decay of Cobalt-60 is through the emission of two gamma rays in cascade at 1.173 MeV and 1.332 MeV. This gamma radiation is very penetrating. A substantial amount of shielding is required to reduce the gamma radiation to safe levels.

The two gamma rays from Cobalt-60 provide the useful radiation in commercial radiation processing equipment. Neither the gamma radiation nor the beta radiation from Cobalt-60 cause any other materials to become radioactive.

5.4 List of references and figures

1. Nordion International. Cobalt 60. (Corporate publication). no date.

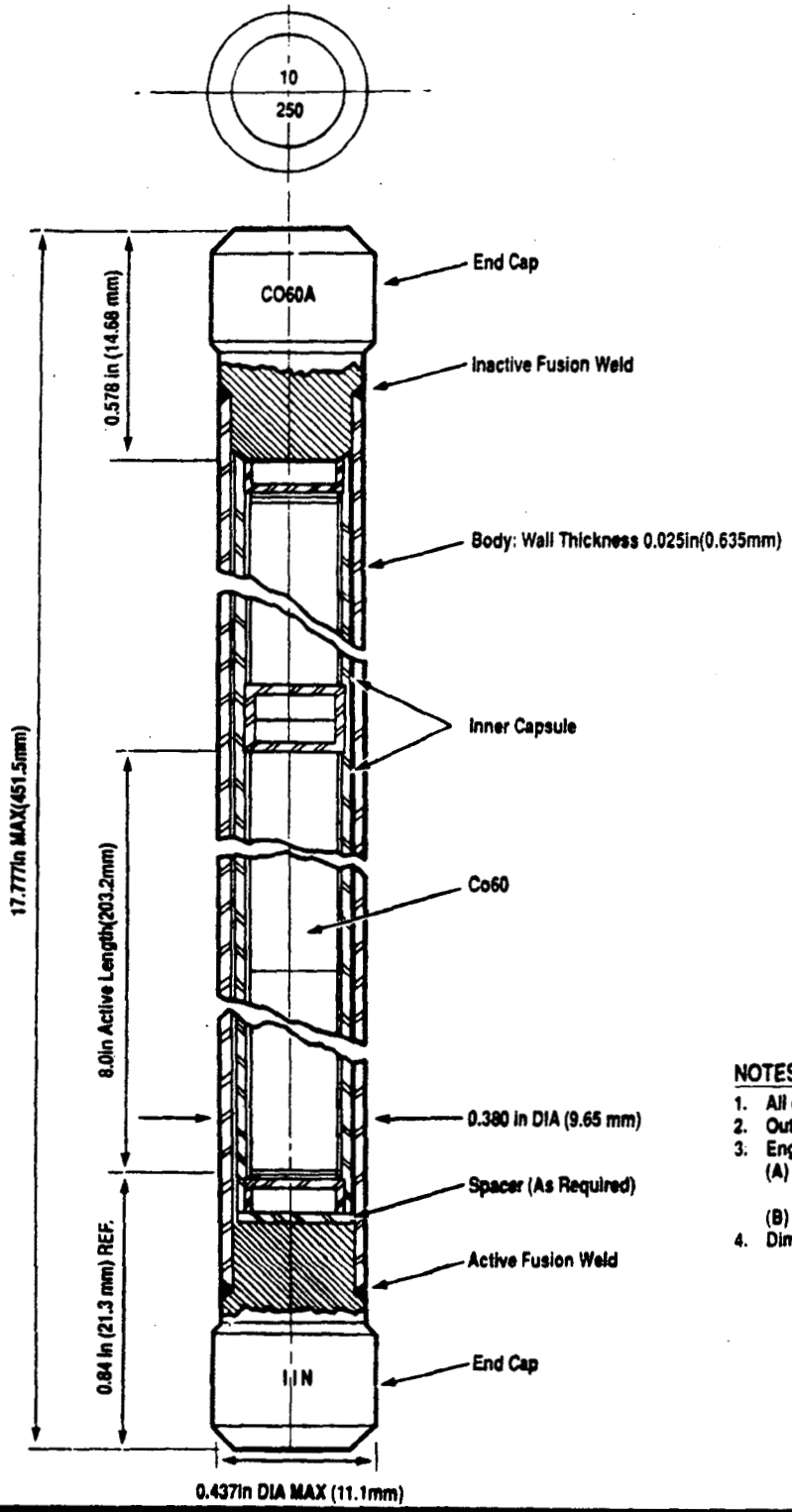
2. Brynjolfsson, A. and Wang, C. P. Atomic Structure. in Josephson, E.S. and Peterson. M. S. Preservation of Food by Ionizing Radiation. V1. CRC Press. 1982.

3. Worswick, J. Cobalt-60 Source Production. Atomic Energy of Canada Ltd. 1983.

4. Kunstadt, P. Transport of Cobalt 60 Industrial Radiation Sources. Nordion International. 1989.

Figure 1. C-188 Source Pencil Assembly. Nordion drawing No. A05244, Issue H.

Figure 1



C-188 Type Number	Model Number of Inners
1	C-177/C-177
2	AC-191/AC-191
3	AC-195/AC-195
4	C-246
5	AC-339/AC-339
6	AC-345/C-348
7	C-177/AC-191
8	C-177/AC-195
9	C-177/AC-339
10	AC-191/AC-195
11	AC-191/AC-339
12	AC-195/AC-339

NOTES:

1. All dimensions in inches & millimeters
2. Outer capsule material #316L stainless steel
3. Engraved on capsule:
   (A) Upper End Cap (face): serial number
   (diameter): CO60A
   (B) Lower End Cap (diameter): Nil
4. Dimensions shown are at 68°F(20°C)

NORDION INTERNATIONAL INC.
447 March Road, P.O. Box 13500
Kanata, Ontario, Canada, K2K 1X8
Tel: (613) 592-2790 • Fax. (613) 592-6937 • Telex. 053-4162

TITLE: SOURCE PENCIL ASS'Y

REF. DWG. AO5244			REVISED 1989 AUGUST		
DATE FEB 3,1967			No. C-188		REV. J
DRAWN D.L.E BLANC	CHECKED	APPROVED	SHEET 1 of 1		

003205

6.0 Introduction of substances into the environment

This section has been divided into two parts. One part deals with the substances introduced into the environment during the production of Cobalt-60. The production is the process which takes Cobalt-60 as it arrives at Nordion from a nuclear reactor to the manufacture of Cobalt-60 capsules for use as a gamma source in an irradiator. Production takes place at Nordion in Canada. It and the transport of radioactive materials in Canada is regulated by a Canadian federal agency, the Atomic Energy Control Board (AECB).

The second part deals with substances introduced into the environment during the use of Cobalt-60 in a gamma irradiator for the irradiation of poultry feed. This part assesses the transport and use of Cobalt-60 as it takes place in the United States.

6.1 For the site of Cobalt-60 production

6.1.1 Substances expected to be emitted.

The following radioactive waste materials are generated during the production of Cobalt-60.

Year	Solid Co-60	Liquid Co-60	Zr-95	Fe-59
1989	15.1 TBq (408 Ci)	34.6 GBq (0.935 Ci)	266 TBq (7193 Ci)	30.9 TBq (835 Ci)
1990	13.2 TBq (356 Ci)	40.0 GBq (1.08 Ci)	316 TBq (8550 Ci)	1.5 TBq (40 Ci)

This waste is disposed of at a radioactive waste disposal site.

The following values of Cobalt-60 activity were released in the environment at Kanata as airborne and liquid effluent.

Year	Airborne	Liquid
1989	0.82 GBq (0.022 Ci)	3.1 GBq (0.084 Ci)
1990	0.3 GBq (0.008 Ci)	0.2 GBq (0.005 Ci)

The regulatory limits are discussed in section 6.1.3, however these release values are small, they are less than 0.5% of the Nordion Derived Release Values, the release limits permitted by the AECB. (See Appendix D for a definition of Derived Limit).

Cobalt-60 is stored, when it is not being shipped, in a pool of water under at least 10.5 feet (3.2 m) of water.

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This water is kept pure by being continuously circulated through an ion exchange system so that there is no corrosion of the Cobalt-60 source capsule. The water in this system is in a closed system. Regeneration of the resin beds of the deionizer is required five times a year. Both acid and alkaline solutions are used to flush the resins in order to strip them of the accumulated cations and anions. For each regeneration about 1500 L of waste water will be produced. The waste acid, alkaline, back wash, and rinse water are collected in a neutralizing holding tank before being released to the sanitary sewer. The waste water will contain sodium chloride from the acid/alkaline (HCL/NaOH) neutralizing reaction and the ions which have been stripped from the deionizer resin. These ions occur mainly as iron salts.

6.1.2 Controls Exercised

6.1.2.1 Introduction

The potentially hazardous nature of Cobalt-60 requires that equipment and procedures for the monitoring and safe operation of the facilities must be provided at all times.

Cobalt-60 is stored under water and is processed in shielded cells behind thick concrete walls and lead glass windows. Remotely controlled manipulators are used to construct the doubly encapsulated C-188 sources used in a gamma irradiator. The air in the cells is filtered through filter banks before being released in the atmosphere. The activity on the filters is continuously monitored. Periodically they are replaced using procedures approved by the AECB in the facility license submission, and disposed of as radioactive material.

The Cobalt-60 is stored in one of two completely separate water pools. One pool is used for sources which have just been activated in the nuclear reactor. The other pool contains the processed doubly encapsulated C-188 pencil cobalt 60 sources which have been tested for the presence of radioactive contaminant material. Only if no radioactivity is found are they stored in the second pool while awaiting shipment. The waste water referred to in section 6.1.1 comes from the second pool only.

The water in the pools is continuously being filtered and deionized so that there will be no corrosion of the source capsules.

There are four types of radioactive waste materials produced, solid Co-60, liquid Co-60, Zr-95 and Fe-59. The

solid waste contains Cobalt-60 on rags, on the bundle holders, and on cell filters. Liquid Cobalt-60 waste contains Cobalt-60 suspended in water used for the decontamination of containers shipped from the reactor and in resin columns used to deionize and filter the water in the receiving pool. Zr-95 is a combination of Zr-95 and Nb-95 which are activation products from impurities in Zircalloy cladding. Fe-59 is an activation product found on the spring clips which hold the cobalt pencils in the bundles.

For decontamination purposes 25 gallons of radiac wash is used in a year (manufacturer: Atomic Products Corp. Shirley, New York 11967). This is disposed of as radioactive waste.

6.1.2.2 Shielding

The gamma radiation is controlled with radiation barriers. Cobalt-60 is stored under at least 10.5 feet (3.2 m) of water. It is processed behind reinforced concrete or leaded glass with remotely controlled manipulators. It is shipped in lead and steel shipping containers.

6.1.2.3 Personnel Training

Personnel engaged in the processing of Cobalt-60 are carefully trained in radiation safety and the safe handling of radioactive materials. Safety courses are provided by Nordion in-house.

6.1.2.4 Access Control

Access into the cell that may contain Cobalt-60 is carefully controlled by interlocks, warning lights and audible alarms to prevent exposure to unwanted levels of radiation. The radiation detection instrumentation is continually checked and recalibrated.

6.1.3 Emissions and occupational health requirements and standards

The Atomic Energy Control Board of Canada has licensed Nordion to have a Derived Release Limit for atmospheric emissions of Cobalt-60 of 5.5 GBq/week (0.15 Ci/wk), and for liquid effluent of 8.0 GBq/month (0.22 Ci/month). The release rates of the radionuclides to the environment satisfy internationally adopted basic principles based on the recommendations issued by the International Commission on Radiological Protection (ICRP) (1). A fundamental principle is that the total dose from all radiation sources to individual members of the public excluding natural background radiation and medical exposure should not exceed

dose limits recommended by the ICRP. Therefore members of the general public have an annual dose limit of 5 mSv.

The Atomic Energy Control Board of Canada has licensed Nordion to have a personal radiation dose legal limit of 5 mSv/yr for the general public and 50 mSv/yr for atomic radiation workers (ARW). The administrative (defined as 'authorized' in reference 1) limit for ARW's is 14 mSv/yr.

Nordion International Inc. has been granted by the AECB a Radioisotope Licence for the "Possession, Importation and Use" of Cobalt-60 (2).

The Nordion International Inc. C-188 Cobalt-60 source capsule, types 1 to 12 inclusive have been granted by the AECB a "Special Form Radioactive Material Certificate Number CDN/0010/S, (REV. 0)" (3), so that it meets the regulatory requirements as defined in the Canadian Transport Packaging of Radioactive Material Regulations and the International Atomic Energy Agency, IAEA, Safety Series No 6 Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition (as amended).

The shipment of C-188 Cobalt-60 sources takes place in F-168 containers. These containers have been approved by the AECB by the Radioactive Material Type B(U) Package Design Approval Certificate No CDN/2012/B(U) (REV.17) (4).

The bulk shipping container, Model F-231, is used to transport Cobalt-60 from the reactor site to the Nordion processing facility. This container has been approved by the AECB by the "Radioactive Material Type B(U) Package Design Approval Certificate No. CDN/2047/B(U), (Rev. 5)"(5).

Radioactive waste is carried from Nordion to the disposal site in an F-339 bulk container. This container is been approved by the AECB by the "Radioactive Material Type B(U) Package Design Approval Certificate No. CDN/2055/B(U), (Rev. 1)".(6)

6.1.4 Quantities and concentrations of substances expected to enter the environment as a result of use or disposal of products as a result of approval of feed irradiation.

In 1989 the total Nordion Cobalt-60 production was 33 MCi (1.22 EBq) in 1990 it was 20 MCi (740 PBq). Approval to irradiate poultry feed will result in a anticipated need to increase the annual production by 4.5 MCi (167 PBq). Using 1990 figures as a basis for comparison it follows that the yearly increase of gaseous emissions of will be 0.068 GBq and the yearly increase of liquid emissions will be 0.045 GBq, giving total releases well below the release limits (section 6.1.3). The amounts released to the atmosphere are

reported on a yearly basis to the AECB. If the amounts increase significantly because of increases in Cobalt-60 production the filtering will be increased to reduce atmospheric emissions.

When the capsules no longer provide sufficient gamma radiation to be useful, when the warranty time expires, or when an gamma irradiator is decommissioned the cobalt pencils are shipped back to the site of production at Kanata, Ontario, Canada for reprocessing or disposal. It is anticipated that the Cobalt-60 sources will be returned after 15 years. Cobalt-60 disposal consists of initially of semi-permanent storage in steel and lead shielded containers and eventually consists of long term permanent storage in especially constructed vaults. The disposal site which is licensed by the Atomic Energy Control Board of Canada is located at Atomic Energy of Canada Ltd, Research Company, Chalk River Ontario (see section 4.4).

Of the annual additional production of 4.5 MCi (167 PBq), 625 kCi (23 PBq) will be shipped back after 15 years to Nordion from the poultry feed irradiators, the remainder will have decayed away. This activity of 625 kCi (23 Pbq) will decay to 3.09×10^{-9} Ci (114 Bq) in 250 years.

6.2 For the site of Cobalt-60 use

The introduction of substances introduced into the environment have been described for a typical Gamma Irradiator used for the irradiation of bulk product.

For irradiation the bulk product may be placed in bags on pallets and irradiated in a pallet irradiator or poured in totes and irradiated in a tote type irradiator or poured into carriers and irradiated in a carrier type irradiator. Since the process is the same for each one of these irradiators the pallet type irradiator is used as an example of a irradiator in this document. This pallet type irradiator has a plaque source which has, for the purpose of this document, a maximum activity of 5,000,000 Ci of Cobalt-60. Note, however, that each irradiator is designed individually, and the actual activity may be greater or smaller than the activity assumed in this document.

For each irradiator to be installed in the United States a license submission has to be made to the U.S. Nuclear Regulatory Commission or the appropriate Agreement State authority. Nordion prepares a licensing information package for its customers to help them to prepare a licensing submission to the appropriate licensing authority. The licensing information package for the sample irradiator is found in Appendix C. The USNRC, Office of Nuclear Regulatory Research, draft regulatory guide FC 403-4,

'Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source, Storage Irradiators' (January 1985) (see Appendix C), Items 5 to 11 have been used as the guide for the information provided. The proposed rule on "Licenses and Radiation Safety Requirements For Large Irradiators" , issued by the USNRC on December 4, 1990 as 10 CFR 36 has also been considered. For a fuller description of the irradiation process see Appendix C Item 9.1(2) "Product Handling".

6.2.1 Substances expected to be emitted

The C-188 Cobalt-60 source capsules only emit gamma ionizing radiation (photons).

Waste water is released into the sanitation sewers when the deionizers for the Cobalt-60 are regenerated. This waste water contains sodium chloride and ions which have been stripped from the deionizer resin beds. The ions are mainly in the form of iron salts. Each regeneration releases about 1500 L of water. Regeneration takes place about once every two or three weeks. This waste water contains no radioactive material.

Noxious gases production is discussed in Appendix C Item 9.2(2) "Ventilation Systems". When the Cobalt-60 source is in the irradiate position a small amount of ozone is produced as air is irradiated by the gamma radiation. The ozone production is expected to be 42 x 10^{-3} ft^3/h/MCi (1.2 x 10-3 m^3/h/MCi) (See Appendix A's Appendix J "Production of Ozone by Large Cobalt Sources" A). Ozone is unstable, it has a half value reduction time of 35 minutes (10). The contribution to the ambient ozone in the atmosphere is minuscule since the minimum reported ozone level anywhere in Canada in 1989 was 0.001 ppm (ref 4) the more typical levels are 0.020 ppm.

6.2.2 Controls Exercised

6.2.2.1 Introduction

The potentially hazardous nature of Cobalt-60 requires that equipment and procedures for the monitoring and safe operation of the facilities must be provided at all times.

6.2.2.2 Shielding

The License Information Package (Appendix C) describes in detail the building which houses the irradiator. This includes the shielding of the Cobalt-60 source both when it is in the irradiate and the non-irradiate (shielded) positions (Item

9.1 (1) and (2)).

The source is in a water pool under at least 10.5 feet (3.2 m) of water when it is in the stored position. The radiation room has thick (about 6 feet) concrete walls. Product access to the room is possible only through a maze with several legs. Penetrations through the shielding are carefully constructed and filled with lead wool.

6.2.2.3 Personnel Training

The training of the personnel is described in Appendix C Item 7. It is prescribed by the USNRC. Nordion can provided courses in irradiator operation and radiation protection. Nordion owns a radiation facility at the Canadian Irradiation Centre in Laval, Quebec, Canada where these courses are giving several times a year on the full size irradiator.

6.2.2.4 Access Control

The control and interlock systems are described in detail in Appendix C Item 9.1 (3). Access to the radiation room is strictly controlled. Personnel entry into the radiation room is only possible after the source has been returned to its fully shielded position.

6.2.2.5 Emergencies

Emergencies which could occur and how to deal with them are described in Appendix C Item 10.4. Unlikely but possible emergency conditions are in this section.

6.2.3 Emissions and occupational health requirements and standards

In the United States radiation limits of Cobalt-60 irradiators have to comply with the United States Nuclear Regulatory Commission 10 CFR Part 20 "Standards for Protection against Radiation". It states that "it is the purpose of the regulations of this part to control the receipt, use, control, use, transfer, and the disposal of licensed material by any licensee in such a manner that the total dose to an individual ... does not exceed the protection against radiation prescribed in the regulation in this part". Paragraph 20.1302(a)(2) states that "the dose in any restricted area for external sources does not exceed 0.002 rem (0.02 mSv) in any one hour.

Nordion irradiators are designed in such a way that the average dose rate received by anyone is less than 0.25 mrem/h (2.5 μSv/h) and that radiation levels up to 2.0 mrem/h (20 μSv/h) are allowed in small areas adjacent to the shield provided that they do not contribute significantly to the personnel dose, see Appendix C "Sample Irradiator Licensing Package" Item 9 9.1 section 5 the subsection entitled "Primary Shielding".

The licensing of Cobalt-60 irradiators is regulated by the USNRC and Agreement States. USNRC regulations applicable to irradiators are in 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR 21, "Reporting of Defects and Non-Compliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 71 Packaging and Transportation of Radioactive Material", See Appendix C The USNRC, Office of Nuclear Regulatory Research, draft regulatory guide FC 403-4, 'Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source, Storage Irradiators' (January 1985) Section 1.2 "Applicable Regulations"

Nordion possesses an USNRC "Material License", license number 54-28275-01 expiration date March 31 1994 (8).

Import and export shipment of for radioactive packages in the United States of America has been authorized by the US Department of Transport. The Nordion certificate number is USA/6320/B(U), Revision 11 (expiration date March 21 1992) (9).

The possession and transportation of radioactive materials may also be regulated by state authorities.

6.2.4 Quantities and concentrations of substances expected to enter the environment as a result of use or disposal of products as a result of approval of feed irradiation.

Ozone produced by the irradiation of air during the irradiation process. As stated in section 6.2.1, the rate of ozone production is 1.2×10^{-3} $m^3/h/MCi$, therefore for each increase of 4.5 MCi an hourly increase of 5.4×10^{-3} m^3 of ozone is expected. This ozone has a limited life, a half value reduction

time of 35 minutes.

1500 L of waste water, as discussed in section 6.2.1, generated by each new water pool for each new irradiator built for this purpose. Each generation takes place every two or three weeks.

Other substance released to the environment are those normally associated with process of moving carriers, totes or pallets into and out of the radiation room and past the source, such as lubricants or hydraulic fluids. This operation is no different from which occurs in a warehouse.

6.3 Statement of Compliance

Nordion International Inc. is in compliance with all pertinent Canadian and American regulations and licenses for the production, use, transport and disposal of Cobalt-60. If the FDA-CVM were to grant approval for the irradiation of poultry feed, Nordion International will continue to be in compliance with all pertinent regulation and licenses.

6.4 List of references

1. ICRP Publication 26. Radiation Protection, Recommendations of the International Commission on Radiological Protection. Pergamon Press for the International Commission on Radiological Protection, 1977.

2. Atomic Energy of Control Board Radioisotope Licence Number 5-11001-92C. Possession, Importation, and Use of the radioactive prescribed substance.... Issued 01/11/90.

3. Atomic Energy of Control Board. Special Form Radioactive Material Certificate No CDN/0010/S REV(0). November 9 1989.

4. Atomic Energy Control Board Certification. Radioactive Material Type B(U) Package Design Approval Certificate NO CDN/2012/B(U) (Rev.17). April 25 1990.

5. Atomic Energy Control Board Certification. Radioactive Material Type B(U) Package Design Approval Certificate No. CDN/2047/B(U), (Rev. 5). August 1990.

6. Atomic Energy Control Board Certification. Radioactive Material Type B(U) Package Design Approval Certificate No. CDN/2055/B(U), (Rev. 1). March 18 1992.

7. Environment Canada. National Air Pollution Surveillance Annual Summary 1989. EPS 7/AP/22. December 1990.

8. U.S. Nuclear Regulatory Commission. Material License Number 54-28275-01. July 12 1989.

9. US Department of Transport. Competent Authority Certification for a Type B(U) Radioactive Materials Package Design Certificate USA/6306/B(U), Revision 11. May 23 1990.

Atomic Energy Control Board | Commission de contrôle de l'énergie atomique

5-11001-92C

RADIOISOTOPE LICENCE / PERMIS RADIOISOTOPE — Licence Number / Numéro de permis

I) LICENSEE

The Atomic Energy Control Board issues this licence to:

Nordion International Inc.
P.O. Box 13500
447 March Road
Kanata, ON
K2K 1X8

hereinafter 'the licensee'.

II) PERIOD

This licence is issued for the period of 01/11/90 to 31/10/92.

III) LICENSED ACTIVITY

This licence is issued for the

POSSESSION, IMPORTATION and USE

of the radioactive prescribed substance or the device containing the radioactive prescribed substance described in Section IV for :

processing, total unsealed source possession limit more than 10 GBq (847)

IV) RADIOACTIVE PRESCRIBED SUBSTANCE

ITEM	DESCRIPTION	POSSESSION LIMIT UNSEALED SOURCES	MAXIMUM ACTIVITY PER SEALED SOURCE	TYPE OF DEVICE
1	Cobalt 60	1110 petabecquerels	n/a	n/a
2	Antimony 124	1110 terabecquerels	n/a	n/a
3	Cesium 137	7400 terabecquerels	n/a	n/a

The amount of radioactivity for the radioactive prescribed substance referred to in each item, or, where more than one such substance is included under that item, the sum of the individual radioactivities, shall not exceed the possession limit for unsealed sources, or the maximum activity per sealed source in accordance with the provisions of the above table.

'Sealed Source'means a radioactive prescribed substance sealed in a capsule or having a bonded cover, the capsule or cover being strong enough to prevent contact with and dispersion of the radioactive material under the conditions of use and wear for which it was designed, and includes the capsule or cover.

When a device is listed opposite a radioactive prescribed substance, the said substance is to be used only in that device.

V) LOCATION

Subject to the conditions of this licence, the radioactive prescribed substance(s) may be

used or stored at:
Cobalt Operation Facility
447 March Road
Kanata, ON

VI) CONDITIONS

In addition to the Atomic Energy Control Regulations, the licensee shall comply with the following conditions:

1. This licence, or a copy thereof, shall be conspicuously posted at all specific locations listed in Section V and shall be available at all other locations where the radioactive prescribed substances listed in Section IV are used or stored.

2. Records of all transactions involving a radioactive prescribed substance shall be forwarded to the Atomic Energy Control Board, upon request, indicating for each shipment:
   a) The name and address of the recipient
   b) The radioisotope licence number of the recipient (if applicable)
   c) The radioactive prescribed substance and radioactivity of each shipment
   d) The date of the shipment

.../ 2

3. Operation of the facility, and the possession and use of radioactive prescribed substances, shall be in accordance with the specifications and requirements stipulated in the documentation listed in Appendix "A".

ATOMIC ENERGY CONTROL BOARD

BY W.R. Brown

W.R. Brown Manager
Radioisotopes and
Transportation Division.

003218

Appendix "A" to Radioisotope Licence 5-11001-92C

1) Letter from F.G. Rice (AECL) to R.J. Walker (AECB), dated 27 January 1984.

2) Letter from F.G. Rice (AECL) to R.J. Walker (AECB), dated 23 March 1984.

3) Letter from R.J. Walker (AECB) to M.G. Brown (AECL), dated 10 August 1984.

Reports

1) "Radiation Safety Procedures Manual", Nordion International Inc., Radiation Safety Branch, Operations' Services, authorized by G.B. Powell, approved by B.J. Jackson, January 1990 Revision 3, including material referenced in Schedule B to the document.

2) "Atomic Energy of Canada Limited, Radiochemical Company, Physical Security Report" by L.W. Harper, dated 15 April 1988.

3) "Cobalt Operations Facility - Safety Analysis Report R65122", Revision 1, prepared by A.A. Marquez-Julio, Revised May 1988 by G.R. Malkoske.

90-3726

Certification

Atomic Energy Control Board | Commission de contrôle de l'énergie atomique

SPECIAL FORM RADIOACTIVE MATERIAL CERTIFICATE NO. CDN/0010/S, (REV. 0)

30-A2-187-0 November 9, 1989

The Atomic Energy Control Board hereby certifies that the capsule, as described below, has been demonstrated to meet the regulatory requirements prescribed for special form radioactive material as defined in the Canadian Transport Packaging of Radioactive Materials Regulations and in the IAEA Regulations*, subject to the following provisions.

CAPSULE IDENTIFICATION

Nordion International Inc. C-188 Capsule, Types 1 to 12 inclusive.

CAPSULE DESCRIPTION

The C-188 capsule, types 1 to 12 inclusive, as shown on Nordion drawing No. A05244, (Issue H) consists of an outer welded stainless steel body with solid end caps containing a variety of welded inner capsules. The overall length is 452 mm. The end cap diameters are 11.1 mm and the body diameter is 9.6 mm. The inner configurations consist of either one or two welded stainless steel or zircaloy capsules containing either 6.35 mm diameter by 25.4 mm long cobalt-60 slugs or 1.0 mm diameter by 1.0 mm long cobalt-60 pellets.

AUTHORIZED RADIOACTIVE CONTENTS

This capsule is authorized to contain not more than 630 TBq (17,000 Ci) of cobalt-60 in slug form or not more than 520 TBq (14,000 Ci) of cobalt-60 in pellet form.

Canada

003220

EXPIRY DATE

This certificate expires October 31, 1994.

W R Brown

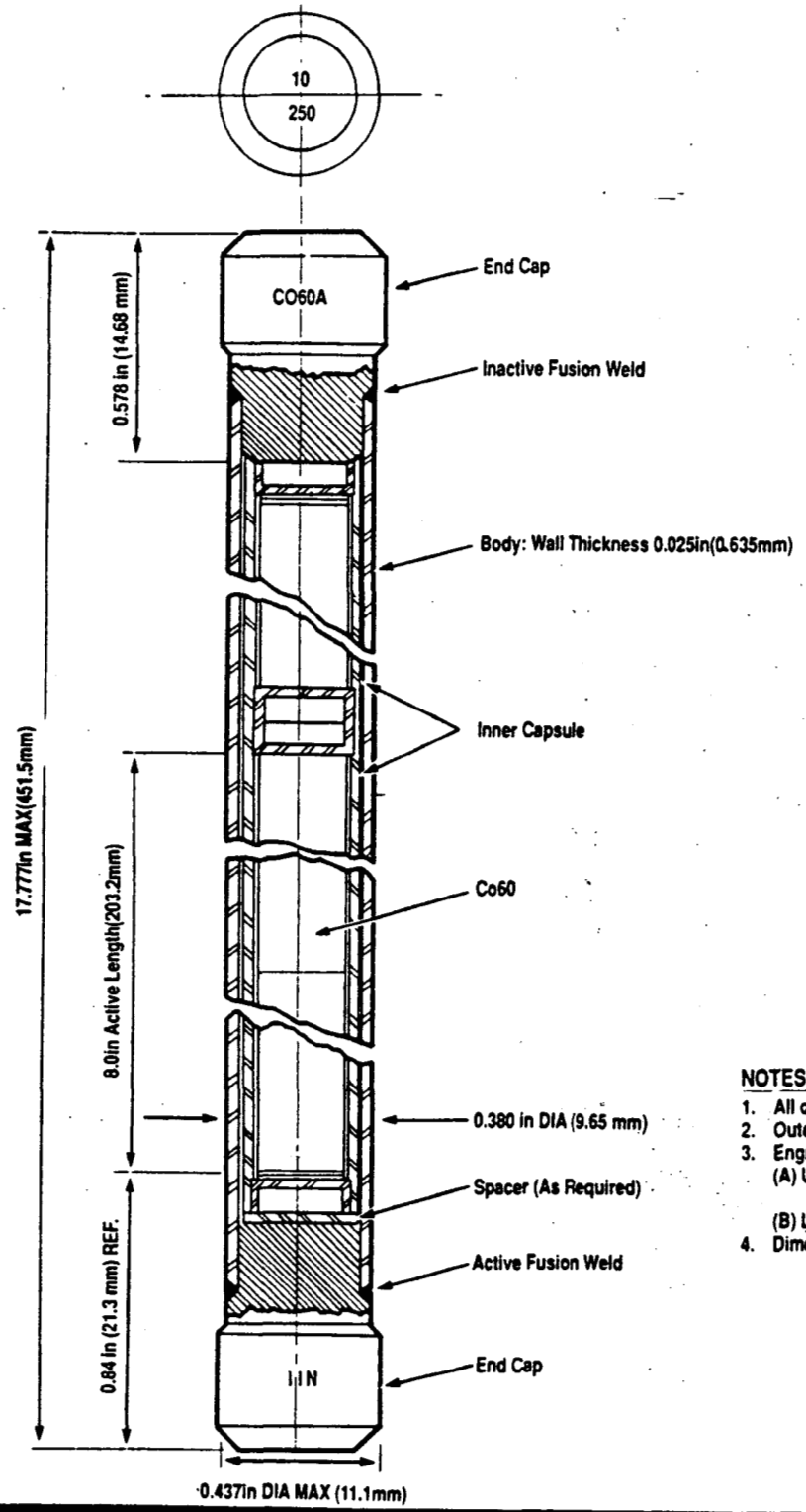
W.R. Brown
Manager
Radioisotopes and Transportation
Division

REFERENCE

* International Atomic Energy Agency Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition (as amended).

NOTES

1. Nordion drawing No. C-188, (Rev. J) attached.
2. Revision 0: November 9, 1989. Original certificate.



C-188 Type Number	Model Number of Inners
1	C-177/C-177
2	AC-191/AC-191
3	AC-195/AC-195
4	C-246
5	AC-339/AC-339
6	AC-345/C-348
7	C-177/AC-191
8	C-177/AC-195
9	C-177/AC-339
10	AC-191/AC-195
11	AC-191/AC-339
12	AC-195/AC-339

NOTES:

1. All dimensions in inches & millimeters
2. Outer capsule material #316L stainless steel
3. Engraved on capsule:
   (A) Upper End Cap (face): serial number
   (diameter): CO60A
   (B) Lower End Cap (diameter): Nil
4. Dimensions shown are at 68°F(20°C)

NORDION INTERNATIONAL INC.
447 March Road, P.O. Box 13500
Kanata, Ontario, Canada, K2K 1X8
Tel: (613) 592-2790 • Fax. (613) 592-6937 • Telex. 053-4162

TITLE: **SOURCE PENCIL ASS'Y**

REF. DWG. AO5244			REVISED 1989 AUGUST	
DATE FEB 3,1967			No. C-188	REV. J
DRAWN D.LE BLANC	CHECKED	APPROVED	SHEET 1 of 1	

003222

Certification

Atomic Energy Control Board | Commission de contrôle de l'énergie atomique

RADIOACTIVE MATERIAL TYPE B(U) PACKAGE DESIGN APPROVAL CERTIFICATE
NO. CDN/2012/B(U), (REV. 17)

30-A2-94-0 April 25, 1990

The Atomic Energy Control Board hereby certifies that the package, as described below, has been demonstrated to meet the regulatory requirements prescribed for Type B(U) packages as described in the Canadian Transport Packaging of Radioactive Materials Regulations and in the IAEA Regulations*, subject to the following provisions.

Each user of this authorization, other than the original applicant, shall register their identity in writing with the Atomic Energy Control Board prior to the first use of this authorization and shall certify that they possess the necessary instructions for preparation of the package for shipment.

This certificate does not relieve the shipper from any requirement of the government of any country through or into which the package will be transported.

PACKAGE IDENTIFICATION

Atomic Energy of Canada Limited, Radiochemical Company F-168 Shipping Flask Nos. 20, 21, 28, 31-33, 35-39, 42 and up.

PACKAGING DESCRIPTION

The F-168 packaging, as shown on AECL-RCC drawing no. F116801-001, (Rev. D), consists of a lead filled (266 mm lead shielding) steel encased right cylinder with external fins, insulated steel flame shields on the top and side and steel covered insulation on the bottom. The package is permanently mounted on a structural steel base. The dimensions are 1013 mm diameter by 1659 mm high, including the removable shipping skid. The gross weight is 5080 kg. The containment system is the source assembly.

This package shall bear the competent authority identification mark "CDN/2012/B(U)".

Canada

AUTHORIZED RADIOACTIVE CONTENTS

This package is authorized to contain not more than:

Radionuclide	Max. Quantity TBq (curies)	Form	Max. Decay Heat (watts)	Encapsulation
Cobalt-60	7,400 (200,000)	metal pellets, metal slugs, stainless steel clad wire, aluminum clad cobalt slugs	3,200	C132, C133, C146, C151, C177, C185, C188, C189, C190, C198, C199, C200, C238, TC239, C246, C247, C248, C252, C306, C335, XC318, XC325,
Cobalt-60	2,590 (70,000)	metal slug aluminum sheathed	1,070	C350 in F359 carrier
Cobalt-60	5,550 (150,000)	metal slug nickel plated	2,320	C351 in F179 carrier with central position empty
Antimony-124	1,850 (50,000)	cast metal	660	C232
Cesium-137	3,700 (100,000)	cesium chloride	522	Special Form with double encapsulation in stainless steel.

Combination loading of the above materials is authorized provided that the sum of the ratios of loaded activity to authorized activity, for all material loaded, does not exceed one.

SHIPMENT

This package shall be prepared for shipment in accordance with AECL Specification No. DS-0517, (Revision E), "Preparation for Shipment F-168 Containers", the Canadian Transport Packaging of Radioactive Materials Regulations and the IAEA Regulations*.

The average surface heat flux of the package with 7,400 TBq of cobalt-60 is 630 W/m^2. For heat fluxes exceeding 15 W/m^2 supplementary arrangements must be made with the carrier to ensure adequate heat dissipation.

003224

EXPIRY DATE

This certificate expires March 31, 1992.

W.R. Brown

W.R. Brown
Manager
Radioisotopes and Transportation
Division

REFERENCE

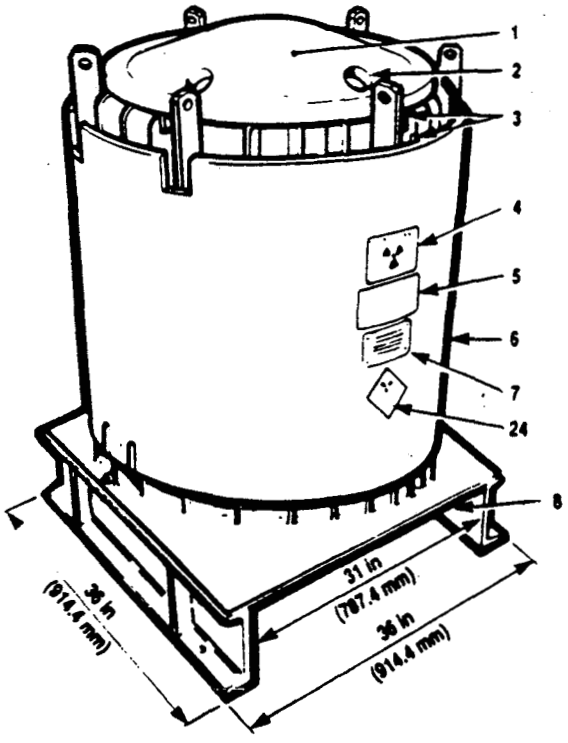
* International Atomic Energy Agency Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition (as amended).

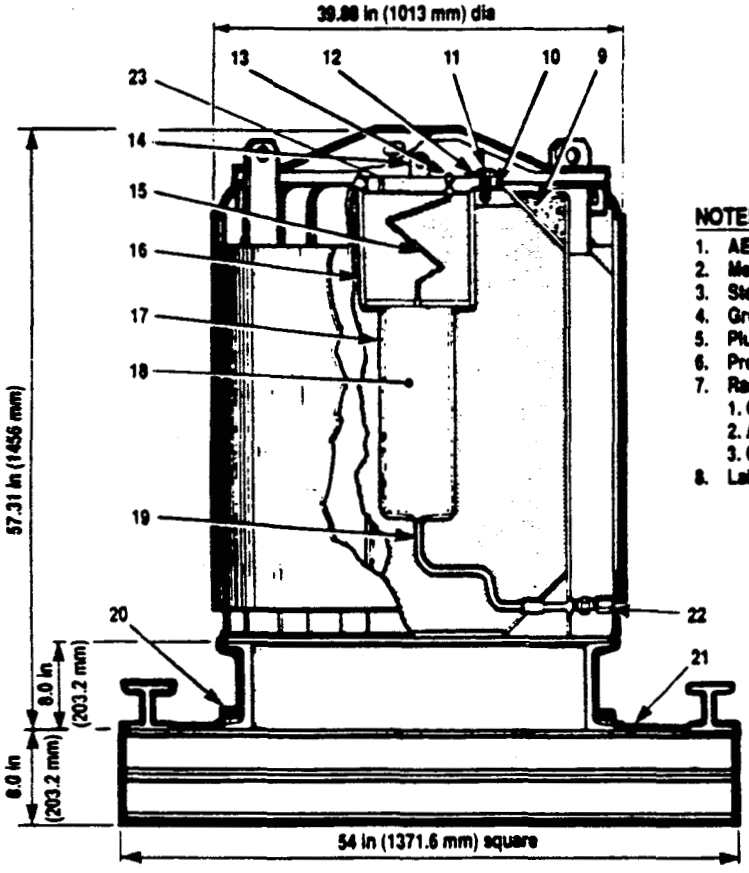
NOTES

1. AECL drawing No. F-168, (Rev. AB) attached.
2. Revision 0: December 1975. Original issue.
3. Revision 10: November 22, 1983. Flask Serial Nos. 70-74 added.
4. Revision 11: February 10, 1984. Type I flame shield container removed and containment system description revised. Certificate renewed.
5. Revision 12: June 10, 1986. Capsules C350, C351 added.
6. Revision 13: August 1, 1986. Flask serial numbers extended.
7. Revision 14: March 19, 1987. Flask serial numbers 24 and 41 deleted.
8. Revision 15: February 9, 1988. Certificate renewed.
9. Revision 16: June 28, 1988. Flask serial numbers revised. Drawing No. F-168 revised.
10. Revision 17: April 25, 1990. Contents revised.

Parts List

1. Heat Cover
2. Holes for Ventilation
3. Retaining Brackets (4) for Heat Cover & Fireshield
4. Radiation Caution Plate
5. Nordion Identification Plate
6. Fireshield (Removable) Laminated Construction:
   2 × ¼ in (6.3 mm) Steel + 1 in (25.4 mm) Kaowool. O.D. 39.88 in (1013 mm)
7. Warning Plate "CAUTION - HEAT EMITTER - DO NOT STORE IN INSULATED OR REFRIGERATION CONTAINER OR INSULATED SPACE"
8. Transite - Steel Encased
9. Vermiculite Packing
10. Gasket (Neoprene)
11. ⅞—9 × 2 in long Hex Bolt (8)
12. Wire Seal
13. ⅜ in NPT Pipe Plug (2)
14. Plug Lift Lug
15. Flush Tube
16. Plug
17. Cavity: 18.87 in × 6.37 in Dia. (479.4 mm × 161.9 mm Dia.)
18. Radioactive Contents and Carrier
19. Drain Tube
20. ¾—10 × 2 in Hex Bolt for Skid (4)
21. Removable Shipping Skid, 54 in (1370 mm) square
22. Nipple and Cap with Drainline Cable and Plug
23. Shield Plate with ⅜—16 Screws (3)
24. Category Label (2)





NOTES

1. AECB Certificate CDN/2012/B(U)
2. Meets IAEA Type B(U) Requirements
3. Steel encased lead shielding: 10.5 in (266 mm)
4. Gross Weight: 11,200 lb (5080 kg)
5. Plug Weight: 380 lb (172 kg)
6. Projected Floor Loading: 553 lb/ft^2 (2700 kg/m^2)
7. Radionuclides carried:
   1. Cobalt-60
   2. Antimony-124
   3. Cesium-137
8. Labels may be positioned as illustrated, or 45° to that shown

NORDION INTERNATIONAL INC.

447 March Road, P.O. Box 13500
Kanata, Ontario, Canada, K2K 1X8
Tel:(613) 592-2790 • Fax:(613) 592-6937 • Telex: 053-4162

TITLE	F-168 Transport Packaging		
REF. DWG.	F116801-001	REVISED	1990 April
DATE	NOVEMBER 1965	No.	F-168
		REV.	AB
DRAWN	CHECKED	APPROVED	
		SHEET 1 of 1	

003226

Certification

Atomic Energy Control Board | Commission de contrôle de l'énergie atomique

RADIOACTIVE MATERIAL TYPE B(U) PACKAGE DESIGN APPROVAL CERTIFICATE
NO. CDN/2047/B(U), (REV. 5)

30-A2-196-0 August 31, 1990

The Atomic Energy Control Board hereby certifies that the package, as described below, has been demonstrated to meet the regulatory requirements prescribed for Type B(U) packages as described in the Canadian Transport Packaging of Radioactive Materials Regulations and in the IAEA Regulations*, subject to the following provisions.

All users of this authorization shall register their identity in writing with the Atomic Energy Control Board prior to the first use of this authorization and shall certify that they possess the necessary instructions for preparation of the package for shipment.

This certificate does not relieve the shipper from any requirement of the government of any country through or into which the package will be transported.

This certificate supersedes all previously issued revisions of CDN/2047/.

PACKAGE IDENTIFICATION

Nordion International Inc. or Atomic Energy of Canada Limited (AECL)
Model F-231, Serial Numbers 7 and up.

PACKAGING DESCRIPTION

The Model F-231 transport packaging as shown on AECL drawing F 102001-001, (Rev. AK) consists of a lead filled, steel encased cylindrical assembly with external fins, surrounded on the sides by an insulated cylindrical fireshield, on the top by a flame shield and screen, and on the bottom by a removable skid. There are vent and drain lines to facilitate wet loading, which are plugged by safety cables and capped.

The cylindrical fireshield consists of 25 mm of "Kaowool" insulation sandwiched in steel and is attached to the packaging assembly by four hex head bolts and eight socket screws. The screen covers the top flame shield and is attached to the cylindrical fireshield. The flame shield is fabricated of steel and is attached to the assembly via four slotted bracket assemblies and hex head steel bolts.

The containment system consists of the capsule assemblies and the cavity of the F-231 packaging. The overall dimensions of the packaging are 1188 mm in diameter by 1460 mm high. The gross mass is approximately 7730 kg.

The package shall bear the competent authority identification mark "CDN/2047/B(U)".

AUTHORIZED RADIOACTIVE CONTENTS

This package is authorized to contain:

1. not more than 14.8 PBq (400,000 Ci) of cobalt-60 metal contained within one of the following:

   a) either AC-195 Type capsules and bundles with 2, 3, or 4 capsules per bundle or AC-339 Type capsules and bundles with up to 6 capsules per bundle carried within a model F-259 eighteen bundle carrier; or

   b) a maximum of 86 AC-345 Type capsules carried within a model F-348 capsule carrier; or

   c) welded stainless steel capsules that meet the requirements of the International Organization for Standardization, International Standard 2919, First Edition, under the classification number E53434 with the capsules retained within a holder that distributes them throughout the cavity volume.

or

2. a) not more than 30 TBq (810 Ci) of aluminum-jacketed cobalt-60 slugs contained within an AECL F-360 containment can. The F-360 can must be sealed with 3M DP-190 epoxy adhesive in addition to the 12 screws; and

   b) miscellaneous nuclides with a total activity not greater than the Type A limits for those nuclides contained within an AECL F-360 containment can. The F-360 can must be sealed with 3M DP-190 epoxy adhesive in addition to the 12 screws.

SHIPMENT

The package shall be prepared for shipment in accordance with AECL Operating Procedures IN/OP 0027 F-231, (Rev. C) "Preparation for Shipment of F-231 Radioactive Material Transport Packages (Wet Loading)" or IN/OP 0034 F-231, (Rev. B) "Preparation for Shipment of F-231 Radioactive Material Transport Packages (Dry Loading)", and the Canadian Transport Packaging of Radioactive Materials Regulations, and the IAEA Regulations*.

The average surface heat flux of this package with 14.8 PBq (400,000 Ci) cobalt-60 is 970 W/m^2. For heat fluxes exceeding 15 W/m^2 supplementary arrangements must be made with the carrier to ensure adequate heat dissipation.

When cobalt-60 slugs are being transported the supplementary loading instructions listed in AECL Report No. TR-F231-87015 must be followed.

EXPIRY DATE

This certificate expires October 31, 1992.

W R Brown

W.R. Brown
Manager
Radioisotopes and Transportation
Division

REFERENCE

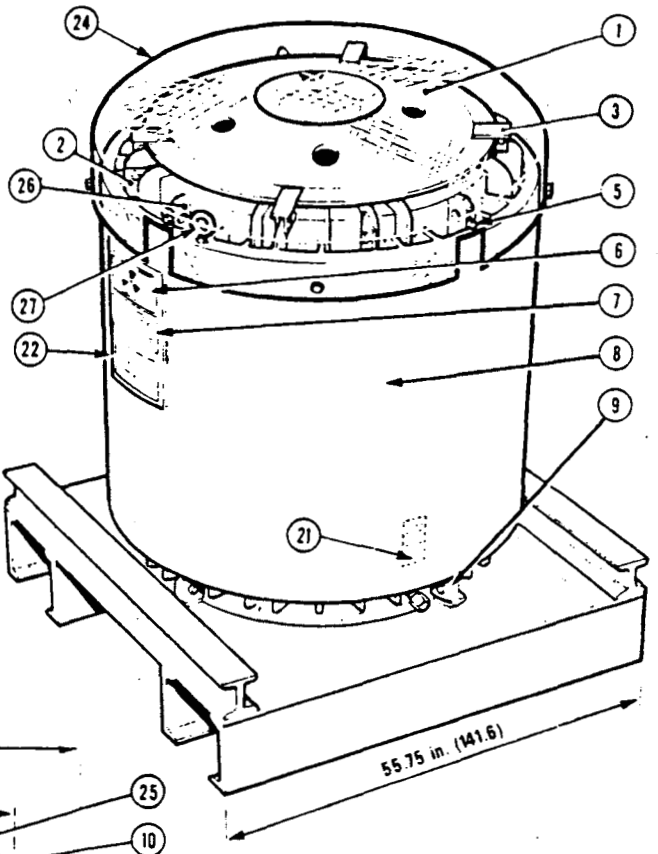
* International Atomic Energy Agency Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition (as amended).

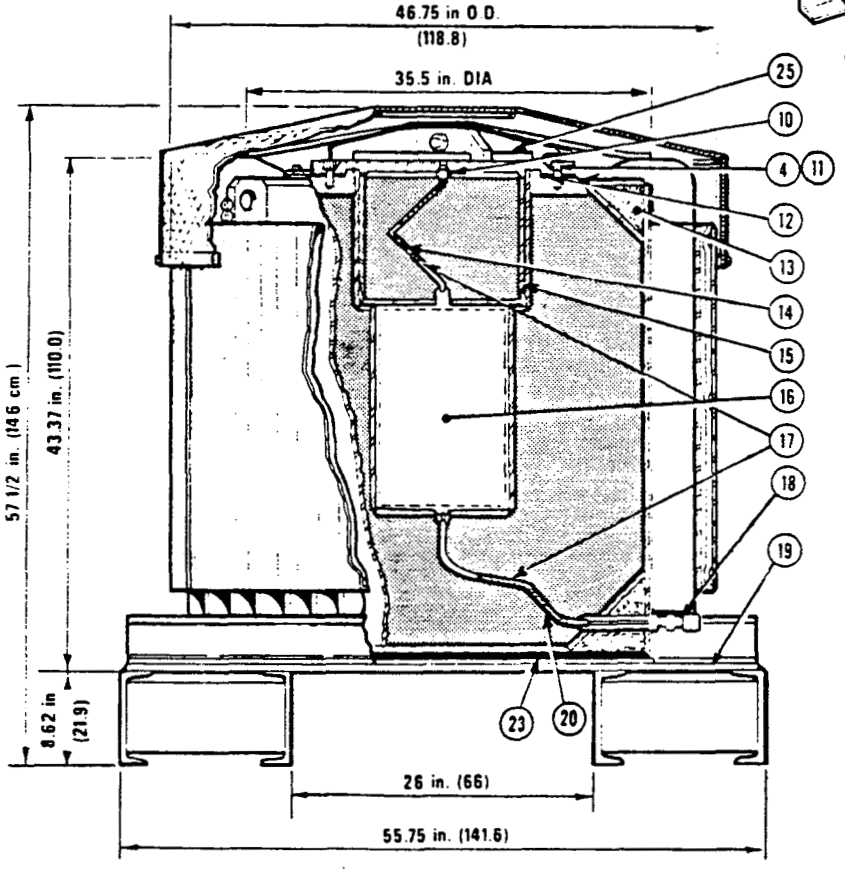
NOTES

1. Drawing No. F-231, Revision K attached.
2. Revision 1: 18 October 1984. Revised Operating Procedure IN/OP 0027 F-231.
3. Revision 2: January 30, 1985. Item c) added to Authorized Radioactive Contents and Preparation for Shipment Operating Procedures revised.
4. Revision 3: October 23, 1987. Cobalt-60 slugs added to Authorized Contents.
5. Revision 4: October 12, 1988. Certificate renewed.
6. Revision 5: August 31, 1990. Registered user requirement added.

NOTES

1. MEETS IAEA TYPE B(U) REQUIREMENTS APPLICABLE TO SERIAL #7 & UP
2. SHIELDING 11.25 in. (28.5 cm.) LEAD-STEEL ENCASED
3. GROSS WEIGHT 17,000 lb. (7730 kg)
4. PLUG WEIGHT - 750 lb (340 kg.)
5. FLOOR LOADING (BASED ON PROJECTED FLOOR AREA) 750 lb/sq ft (0.38 kg/sq cm.)
6. MAXIMUM CONTENTS - 400,000 Ci Co^{60} IN REMOVABLE CARRIER
7. SAFETY CABLE PLUGS USED IN BOTH VENT & DRAIN TUBE
8. WARNING PLATE "SAFETY CABLE PLUGS MUST BE USED WHEN SHIPPING CONTAINER LOADED"
9. DIMENSIONS IN BRACKETS ARE IN CENTIMETRES





PARTS LIST

1. SHIELD CAP WITH VENT HOLES
2. RETAINING BRACKETS FOR FIRESHIELD (4) - 1 in.-8 x 2 in. LG HEX HD BOLT WASHER, NUT
3. RETAINING BRACKETS FOR SHIELD CAP (4) - 3/8-16 x 1-1/2 in. LG HEX HD BOLT, WASHER, NUT
4. PLUG SCREWS - 3/4 x 1-3/4 in. LG SOCKET HD (8) AND 7/8 - 9 x 2-1/2 in. LG HEX HD (2)
5. FIRESHIELD RETAINING SCREWS (8) - 1/2-13 x 1 in. LG SOCKET HD
6. RADIATION CAUTION PLATE - AECL SPEC DG0096 (2)
7. AECB CERTIFICATION PLATE - AECL SPEC DG0097 (2)
8. REMOVABLE FIRESHIELD
9. 3/4-10 x 2 in. LG HEX HD BOLTS (4)
10. 3/8 in. NPT PIPE PLUG AND SAFETY CABLE
11. WIRE SEAL INSTALLED THROUGH HEADS OF HEX HEAD BOLTS (ITEM 4)
12. NEOPRENE GASKET
13. VERMICULITE
14. VENT TUBE
15. REMOVABLE PLUG
16. CAVITY 11.5 x 17.5 in. (29.2 x 44.5 cm.)
17. SAFETY CABLES
18. CAP & NIPPLE ON END OF DRAIN LINE
19. REMOVABLE SHIPPING SKID
20. DRAIN TUBE
21. WARNING PLATE (SEE NOTE 8)
22. WARNING - STORAGE PLATE - AECL SPEC A14649(2)
23. TRANSITE (STEEL ENCASED) INSULATION
24. HEAT SCREEN & ATTACHMENT SCREWS, 3/8-16 x 3/4 in LG (4)
25. CRACK SHIELD RING
26. LIFTING/TIE-DOWN LUGS (4)
27. EYEBOLTS (2)

ATOMIC ENERGY OF CANADA LIMITED
413 MARCH ROAD, P.O. BOX 13500,
KANATA, ONTARIO, CANADA, K2K 1X8
Telex: 053-4982 Cable: NEMOTA
Tel. (613) 592-2790

TITLE

F-231 TYPE B(U) TRANSPORT PACKAGING

REF. DWG. F102001-001			REVISED OCTOBER 1986	
DATE 11 JUNE 1973			No. F-231	REV. K
DRAWN KB	CHECKED	APPROVED	SHEET 1 OF 1	

003230

Certification

Atomic Energy Control Board | Commission de contrôle de l'énergie atomique

RADIOACTIVE MATERIAL TYPE B(U) PACKAGE DESIGN APPROVAL CERTIFICATE
NO. CDN/2055/B(U)-85, (REV. 1)

30-A2-227-0 March 18, 1992

The Atomic Energy Control Board hereby certifies that the package, as described below, has been demonstrated to meet the regulatory requirements prescribed for Type B(U) packages as described in the Canadian Transport Packaging of Radioactive Materials Regulations and in the IAEA Regulations*, subject to the following provisions.

Each user of this authorization, shall register their identity in writing with the Atomic Energy Control Board prior to the first use of this authorization and shall certify that they possess the necessary instructions for preparation of the package for shipment.

This certificate does not relieve the shipper from any requirement of the government of any country through or into which the package will be transported.

PACKAGE IDENTIFICATION

Nordion F-339 Transport Package, Serial Nos. 1 and up.

PACKAGING DESCRIPTION

The F-339 Transport Package, as shown on Nordion drawing no. F133902-200, (Rev. B), consists of a lead shielded stainless steel double walled verticle containment cylinder with bolted end plugs of similar construction on the top and bottom. This cylinder is contained within cylindrical double walled thermally insulated cocoons bolted at the centre. Annular wooden impact limiters covered with steel sheeting are bolted to both cocoons. The bottom impact limiter is mounted on a skid. Lifting shackles and tie-down fittings are on the top cocoon. The overall dimensions of the package, including the impact limiters and skid, are 1753 mm high by 1378 mm diameter. The package has a gross mass of 4636 kg.

The package shall bear the competent authority identification mark "CDN/2055/B(U)-85".

AUTHORIZED RADIOACTIVE CONTENTS

This package is authorized to contain any one of the radioactive contents described in Table 1 attached and is further limited to contain less than 15 grams of fissile material.

Canada

003231

Canada

SHIPMENT

This package shall be prepared for shipment in accordance with Nordion Procedure no. IN/PP 0084 F339, (Rev. C) "Preparation for shipment of the F339 Type "B" Transport Package", the Canadian Transport Packaging of Radioactive Materials Regulations, and the IAEA Regulations*.

EXPIRY DATE

This certificate expires June 30, 1995.

W R Brown

W.R. Brown
Manager
Radioisotopes and Transportation Division

REFERENCE

* International Atomic Energy Agency Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1985 Revised Edition (as amended).

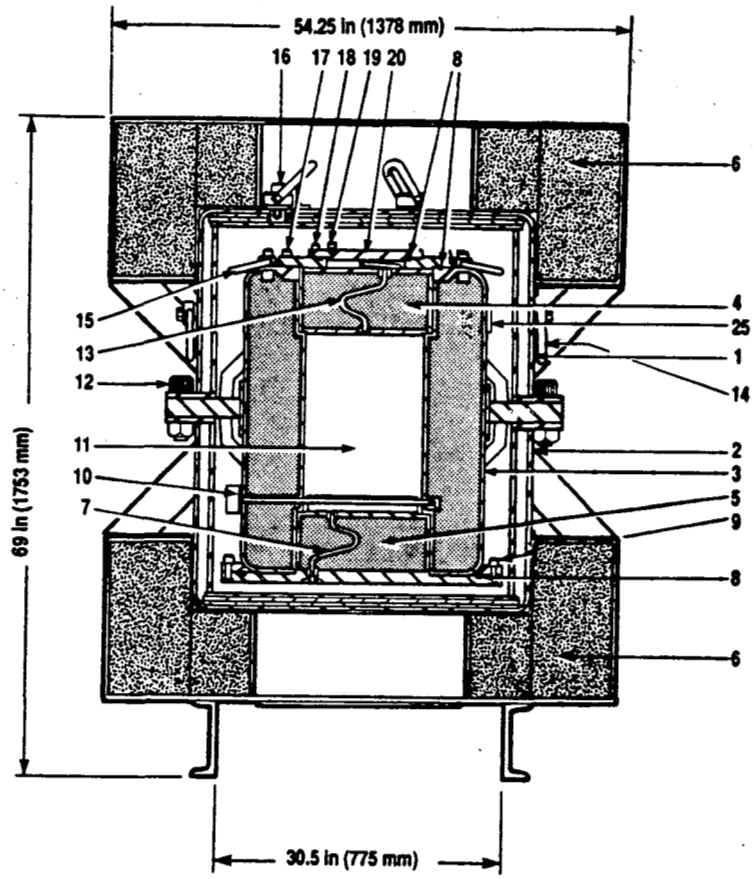
NOTES

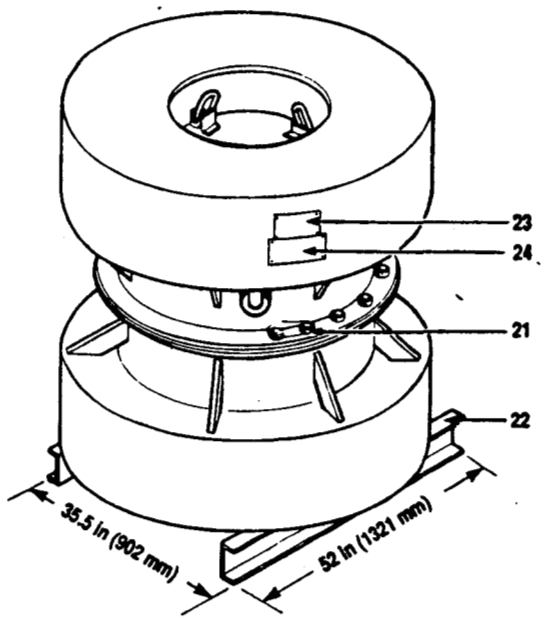
1. Nordion drawing no. F-339, (Rev. A) attached.
2. Revision 0: June 6, 1991. Original issue.
3. Revision 1: March 18, 1992. Typographical Error.

003232

TABLE 1
AUTHORIZED RADIOACTIVE CONTENTS

CONTENTS	DESCRIPTION	ACTIVITY
1.	Activated metal scrap	Up to 320 TBq of Zr-85, Nb-95, Fe-55, Cr-57, Co-60, Ta-82 and other activation products present in irradiated zircaloy and in stainless steel alloys.
2.	Co-60 Cell Waste	Equivalent to the radiation dose from 5 TBq of Co-60.
3.	I-131 Process Waste	37 GBq Te-121m, 370 GBq Te-121, 2.78 TBq Te-123, 4.44 TBq Te-127m, 2.96 TBq Te-129m, 37 GBq I-131 and activation products less than A_2.
4.	Mo-99 Process Waste	74 TBq Mo-99, 740 GBq I-131, 74 GBq Ru-103 and fission products less than A_2.
5.	Ir-192 Process Waste	74 TBq Ir-192 and activation products less than A_2.
6.	Sr-82 Process Waste	3.7 TBq total of Co-56, Co-58, Cr-51, Nb-92m, Nb-95, Rb-82, Rb-83, Sr-82, Sr-85, V-48, Y-88, Y-89, Y-91, Zr-88, Zr-89 and small amounts of other radionuclides contained in proton irradiated molybdenum powder and associated target shells.





Parts List

1. F-339-02 Upper Cocoon with Impact Protection
2. F-339-02 Lower Cocoon with Impact Protection
3. F-339-01 Shielding Vessel
4. Removable Top Plug
5. Removable Bottom Plug
6. Wooden Impact Protection
7. Drain Tube (both ends plugged)
8. O-Ring Seals (3 locations)
9. Bottom Plug Screws (12) 5/8–11 × 1¾ in long
10. Release Rod Assembly with 'O'-Ring or Gasket
11. Cavity 12.75 in. Dia x 17.5 in. high (324 mm dia x 445 mm high)
12. Cocoon Closure Screws (12) 1½–6 × 5 in. long
13. Cable Tube
14. Tiedown Rings (4 locations, shown out of position)
15. F-339-01 Safety Hoist Rings (2)
16. F-339-02 Safety Hoist Rings (3)
17. Top Plug Screws (12) 5/8–11 × 1¾ in. long
18. Top Plate Screws (8) 3/8–16 × 1¼ in. long
19. Top Plate Plug
20. Top Plate
21. Wire Seal Between Two Adjacent Bolts
22. Skid
23. AECB Certification Plate - 2 locations
24. Radiation Caution Plate - 2 locations
25. F-339-01 Identification Plate and Radiation Caution Plate

Notes

1. Meets IAEA Type B(U) Requirements
2. Shielding Vessel: 5.88 in(149 mm) lead, encased between 0.38 in. (10 mm) stainless steel walls
3. Projected Floor Loading (based on projected area of skids): 3891 kg/m^2 (796 lb/ft^2)
4. Contents:
   1. Activated Metal Waste
   2. Miscellaneous Cell Waste
5. AECB Type B(U) Certificate No. CDN/2055/B(U)

Component Weights

	kg	lb
Contents (max. weight)	18	40
F-339-01		
Top Plug	236	520
Main Body	2,391	5,260
Bottom Plug	300	660
Total	2,927	6,440
F-339-02		
Upper Cocoon	823	1,810
Lower Cocoon	868	1,910
Total	1,691	3,720
OVERALL TOTAL	4,636	10,200

NORDION INTERNATIONAL INC.
447 March Road, P.O. Box 13500
Kanata, Ontario, Canada, K2K 1X8
Tel: (613) 592-2790 • Fax. (613) 592-6937 • Telex. 053-4162

TITLE: **F-339 Type B(U) Transport Packaging**

REF. DWG. F133902-200			REVISED 1991 March	
DATE 1988 MARCH			No. F-339	REV. A
DRAWN JK	CHECKED MK	APPROVED GAB	SHEET 1 of 1	

003234

NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10 Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Nordion International Incorporated 447 March Road 2. P.O. Box 13500 Kanata, Ontario, Canada K2K 1X8	In accordance with letter dated June 2, 1989, 3. License number 54-28275-01 is amended in its entirety to read as follows:
	4. Expiration date March 31, 1994
	5. Docket or Reference No. 030-30788

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cesium 137	A. Sealed sources (AECL/Nordion)	A. See Condition 10
B. Cobalt 60	B. Sealed sources (AECL/Nordion)	B. See Condition 10

9. Authorized use

A. and B. For storage and/or possession in U.S. Department of Transportation or U.S. Nuclear Regulatory Commission approved shipping containers, AECL/Nordion irradiators, or AECL/Nordion source drawers incident to the performance of the activities specified below involving AECL/Nordion irradiators specified in Condition 10 of this license.

(1) Distribution to persons who are authorized to receive the licensed material pursuant to terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or any Agreement State.
(2) Installation into and/or removal from irradiators and packaging for shipment.
(3) Radiation surveys of irradiators and facilities.
(4) Leak testing of sealed sources.
(5) Decontamination of Irradiators and facilities.
(6) Installation, relocation, removal, repair, maintenance, and operational testing of irradiator units.
(7) Instruction of personnel in the operation of irradiator units.

003235

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 54-28275-01

Docket or Reference number: 030-30788

Amendment No. 01

(Continued)

CONDITIONS

10. The activities authorized by this license are applicable to the following irradiator units and specifications:

AECL/Nordion Irradiator Unit Model Numbers	Isotope	Sealed Source Model Number	Maximum Permissible Activity Per Unit (curies)
Any wet-source-storage irradiator	Cobalt 60	C-188	Not to exceed 14,250 curies per source and as per regulatory approval on design capacity
Gammabeam 100A, 100B or 100C	Cobalt 60	C-230	1,570
Gammabeam 150A, 150B or 150C	Cobalt 60	C-174A or C-174B	6,600
Gammabeam 650	Cobalt 60	C-252	50,000
Gammacell 10 (formerly Radiation Machinery Model 50 or 50B)	Cesium 137	ORNL-RAMCO-50	400
Gammacell 20	Cesium 137	C-161, Type 4	2,300
Gammacell 40	Cesium 137	C-161, Type 8	4,200
Gammacell 100	Cobalt 60	C-170 or C-171	1,000
Gammacell 200	Cobalt 60	C-170, C-171 C-199 or C-200	10,000
Gammacell 220	Cobalt 60	C-166, C-167 C-185 or C-198	26,400
Gammacell 1000 Model A	Cesium 137	ORNL-RAMCO-50 ISO-1000	828 600 ± 20%
Gammacell 1000 Model B	Cesium 137	ORNL-RAMCO-50 ISO-1000	1632 1200 ± 20%
Gammacell 100 Model C	Cesium 137	ORNL-RAMCO-50 ISO-1000	2448 1800 ± 20%
Gammacell 1000 Model D (formerly Radiation Machinery Model M.)	Cesium 137	ORNL-RAMCO-50 ISO-1000	3264 2400 ± 20%

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
54-28275-01

Docket or Reference number
030-30788

Amendment No. 01

(Continued) CONDITIONS

11. Licensed material shall be used only at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.

12. A. Licensed material shall be used by, or under the supervision and in the physical presence of anyone designated by R. G. McKinnon, F. M. Fraser, or B. J. Jackson in accordance with the experience and training requirements specified in the licensee letter dated February 16, 1989. The licensee shall maintain a list of all designated individuals, and records of their training. Designated individuals at temporary job sites shall have copies of their authorization certificate at the site and available for inspection.

B. The Radiation Safety Officer for this license is B. J. Jackson.

13. Sealed sources containing licensed material shall not be opened.

14. A. Any sealed source(s) or detector cell(s) specified in Item(s) 7.A. and 7.B. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source or detector cell received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

B. Any sealed source or detector cell in storage and not being used need not be tested. When the source or detector cell is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source or detector cell shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 54-28275-01

Docket or Reference number 030-30788

Amendment No. 01

(Continued) CONDITIONS

15. Written instructions contained in Appendix III to the application dated December 9, 1983, in the application and attachments dated January 15, 1985, and in the AECL/Nordion (Isomedix) Instruction Manuals for the Gammacell 10 and/or the Gammacell 1000, and in the AECL/Nordion Instruction Manual for the Gammacell 1000, as appropriate, shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for licensed material. Any changes in these instructions shall have the prior approval of the U.S. Nuclear Regulatory Commission, Region I, Nuclear Materials Section, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

16. After installation of the irradiator and/or Cobalt 60 or Cesium 137 source(s) and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. For wet-source-storage irradiators, the survey specifications contained in Appendix III (AECL/Nordion specification DS0418, Revision B) of the application dated December 9, 1983, shall be followed.

17. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated December 9, 1983
B. Application dated December 13, 1983
C. Letter dated May 29, 1984
D. Letter dated January 10, 1985
E. Application dated January 15, 1985
F. Applications (3) dated December 19, 1988
G. Letter dated February 17, 1989
H. Letter dated June 2, 1989

For the U.S. Nuclear Regulatory Commission
Original Signed By:
By Laurence F. Friedman, Ph.D.
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

Date JUL 12 1989

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U.S. Department of Transportation
Research and Special Programs Administration

400 Seventh Street, S.W.
Washington, D.C. 20590

COMPETENT AUTHORITY CERTIFICATION FOR A TYPE B(U) RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/6306/B(U), REVISION 11

REVALIDATION OF CANADIAN COMPETENT AUTHORITY CERTIFICATE CDN/2012/B(U)

This certifies that the radioactive materials package design described below is hereby approved for use within the United States for import and export shipments only. Shipments must be made in accordance with the applicable regulations of the International Atomic Energy Agency[1] and the United States of America.[2]

1. Package Identification - Atomic Energy of Canada Limited, Radiochemical Company P-168 Shipping Flask Nos. 20, 21, 28, 31-33, 35-39, 42 and up.

2. Packaging Description and Authorized Radioactive Contents - as described in Canadian Certificate of Competent Authority CDN/2012/B(U), Revision 17.

3. GENERAL CONDITIONS -

   a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation in accordance with the endorsed certificate.

   b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Radioactive Materials Branch (DHM-23), Office of Hazardous Materials Transportation, Research and Special Programs Administration, U.S. Department of Transportation, Washington D.C. 20590.

   c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.

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1 "Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition, as amended," published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

2 Title 49, Code of Federal Regulations, Parts 100 - 199, United States of America.

d. This certificate is issued only to authorize transport from point of entry to final destination within the United States and from point of origin in the United States to point of exit.

4. Marking and Labeling - The package shall bear the marking USA/6306/B(U) in addition to other required markings and labeling.

5. Expiration Date - This certificate expires on March 31, 1992.

This certificate supersedes, in its entirety, all previously issued revisions of USA/6306/B(U).

This certificate is issued in accordance with paragraph 806 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the April 30, 1990 petition by Nordion International Inc., Kanata, Ontario, Canada, and in consideration of other information on file in this Office.

Certified by:

Michael E. Wangler

MAY 23 1990
(DATE)

Michael E. Wangler
Chief, Radioactive Materials Branch
Office of Hazardous Materials Transportation

Revision 11 - Issued to incorporate Canadian Package Design Approval Certificate No. CDN/2012/B(U), Revision 17.

Appendix A List of preparers

This environmental assessment was primarily prepared by Gerry Van Dyk with contributions from Michelle Marcotte, both of Nordion International Inc.

This Environmental Assessment was reviewed for accuracy and approved by the Nordion Irradiator Engineering Branch and Nordion Management.

ENVIRON Corporation, Arlington, Virginia, regulatory consultants advised Nordion on the preparation of this document.